Controlling Drug Expenditure in Canada
The Ontario Experience

Paul K. Gorecki

A study published by the
Economic Council of Canada
and the
Ontario Ministry of Health

Controlling Drug Expenditure in Canada

92-07008/

Canadian Cataloguing in Publication Data

Gorecki, Paul K., 1948-

Controlling drug expenditure in Canada: the Ontario experience

Issued also in French under title: Le contrôle des coûts des médicaments au Canada.
Includes bibliographical references.
ISBN 0-660-14437-9
DSS cat. no. EC22-183/1992E

1. Prescription pricing – Canada. 2. Drugs – Prices – Canada. 3. Pharmaceutical policy – Canada. 4. Pharmaceutical policy – Ontario. I. Economic Council of Canada. II. Title.

HD9670.C62G67 1992 338.4'36151'0971 C92-099671-X

PAUL K. GORECKI

Controlling Drug Expenditure in Canada

The Ontario Experience

The findings of this study are the personal responsibility of the author and, as such, have not been endorsed by the Economic Council of Canada or the Ontario Ministry of Health.

© Minister of Supply and Services Canada 1992

Available in Canada through

Associated Bookstores
and other booksellers

or by mail from

Canada Communication Group – Publishing
Ottawa, Canada K1A 0S9

Catalogue No. EC22-183/1992E
ISBN 0-660-14437-9

Imprimé au Canada

Contents

Acknowledgments		**ix**
Foreword		**xi**
1	**Introduction**	**1**
	Drugs and Health-Care Costs	2
	Provincial Drug Expenditure	2
	The Changing Balance: Private and Public Drug Expenditure	3
	Provincial Drug Programs: A Thumbnail Sketch	3
	Why Have Drug Program Costs Risen: A Top-Down Approach	7
2	**Problems, Causes, Solutions, and Choices**	**9**
	The Issues	9
	The Causes	9
	Total Expenditure	9
	Quantity	11
	Intensity of Care	11
	A Sense of Perspective	14
	The Solutions	17
	The Approach	18
	Access	18
	Economic Efficiency	18
	Program Administration	19
	Value for Money: Monitoring Outcomes	19
	The Role of the Patient/Consumer	19
	The Role of the Ministry of Health	20
3	**Government Intervention in the Ontario Drug Market: Origins, Evolution, and Rationale**	**21**
	Prescriptions at Reasonable Cost and Product Selection, 1969-74	21
	Federal Initiatives	21
	Pharmacy Initiatives	21
	Provincial Initiatives	21
	Commentary	23
	The Ontario Drug Benefit Program: 1974-76	23
	The Rationale for the ODB	24
	Solving Problems: Drug Prices, Dispensing Fees, Dispense Quantity as Written, 1976-86	26
	Purchasing Advantage and Price-Spread	26
	The Bailey Committee	26
	The Gordon Commission	27
	The Role of Government	29
	The Solution: Bills 54 and 55	30

The Ontario Drug Benefit Act 30
The Prescription Drug Cost Regulation Act 31
The Influence of the Bailey Committee and the Gordon Commission 32
Developments since 1986 33

4 **Dispensing Fees, Professional Services, and Patient/Consumer Copayments** **35**
Setting the Dispensing Fee 36
Institutional Framework 37
Determination of the Fee 37
The Impact of the 1986 Legislation on Quantity Dispensed 39
The Result: No Change in Quantity Dispensed 39
Why Was There No Change in Quantity Dispensed? 42
A Successful Dispense-as-Written Policy: B.C. Pharmacare 43
Policy Prescription 44
Public Parsimony at Private Expense? 44
Determining the ODB Fee: Does the Process Work? 46
Can Pharmacy Dispensing Costs Be Estimated? 46
Determining the Import of Cost Levels 49
Alternative Methods of Setting the Dispensing Fee 50
A Competitive Retail Market 50
Other Copayment Mechanisms 54
Auctioned Franchises 55
Capitation 55
Impact 56

5 **Drug Reimbursement Systems: Best Available Price, Actual Acquisition Cost, and Standing Offer Contracts** **59**
The ODB Reimbursement System 59
Best Available Price 59
Mark-Up 60
Price and Product Selection Rules 60
Pharmacy Reimbursement 60
Eliminating the Spread: Has the BAP Been Successful? 61
The Impact of the BAP on ODB Drug Prices 61
Ontario's BAP Compared with Saskatchewan's SOC 63
Evidence on the Spread 66
Whither the Spread? 67
Beyond the BAP: Are There Better Alternatives? 68
The Problem with the BAP: Incentive Incompatibility 68
Minor Adjustments: Market-Assessed Price, Price Monitoring, and a Single Formulary Price 69
Actual Acquisition Cost: A More Far-Reaching Change 70
Major Change: A Tendering System 77
Major Change: Mandating Prices 79

6 **There Is More than One Way to Skin a Cat: Brand-Name Firm Marketing Strategies** **83**
Promoting Brand Loyalty: No-Substitution Prescriptions 83
The Importance and Cost of No-Substitution Prescriptions 83

No-Substitution Prescriptions: A Formal Analysis 84
Assessment 86
Policy Options 87
Pricing Strategies 88
Fighting Brands 88
Policy Options 101
Shifting Demand: Long-Acting or Slow-Release Dosage Forms 101
The Incidence and Importance of Modified Release Dosage Forms 102
Assessment 103
Policy Options 103
Conclusions 104

7 Promoting Cost-Effective Prescribing 107
Rationale for Intervention 107
The Prescribing Decision 107
The Influence of Cost on Drug and Brand Choice 110
Cost-Effective Prescribing: Process, Criteria, and Implementation Mechanisms 112
The Process 112
The Criteria 115
Overview 116
Administrative Matters: the Role and Responsibilities of the DQTC 117
Procedural Fairness and Timeliness 117
Procedural Safeguards 117
Criteria for Cabinet Intervention 118
Communicating with Its Public 118
How the Leaky Boat Finally Sank: Special Authorizations 118
Assessment 119
Reforming Special Authorizations: Nonformulary Benefits 119
Interchangeability 120
Pricing the First Lower-Priced Interchangeable Brand 120
Evaluating the Concerns about Interchangeability 121
New Directions 124
Criteria for Eligibility of Single-Source Drug Products 124
Improving Physician Prescribing 126
New Directions: Full of Sound and Fury Signifying Nothing? 128

8 Conclusions 129

A Terms of Reference and Recommendations of the Review Committee on Prescription Product Substitution (Porter Committee) and the Ontario Drug Benefit Formulary Pricing Committee (Bailey Committee) 131

Notes 135

List of Tables and Figures 147

Glossary and Abbreviations of Dosage Forms 151

Bibliography 153

Acknowledgments

I would like to thank the Economic Council of Canada and the Pharmaceutical Inquiry of Ontario for supporting this study. An earlier version appeared as a background paper for the Pharmaceutical Inquiry. The Council not only allowed secondment for that purpose but also provided the time for me to complete the present study.

A large number of people have given generously of their data, time, advice, and comments. It is not possible to name all those who have provided assistance, but I would particularly like to thank the following individuals: Tom Ashby, Alan Burrows, David Chown, Yale Drazin, Perry Fisher, Tom Horlor, Ron Paquin, Barbara Tisdale, and Gordon Ventura (the Ontario Ministry of Health); Michelle Chibba (formerly of the Pharmaceutical Inquiry of Ontario); Ron Corvari and John Baldwin (the Economic Council of Canada); Peter A. Croden (the Upjohn Company of Canada); Jim Cuttle (Kenral); Murray D. Shantz (the Pharmaceutical Advertising Advisory Board); Brenda Drinkwater (Novopharm); John Harvey (Eli Lil'y Canada); S. George Carruthers (Victoria General Hospital, Nova Scotia); Fay MacKie (New Brunswick Prescription Drug Program); Vern Hicks and E. Hubbard (Nova Scotia Pharmacare); Jack Kay and Barry Sherman (Apotex); Loree Marcantonio (B.C. Pharmacare); Tom Brogan (Brogan Consulting); Robert Metras (formerly of the Ontario Pharmacists' Association); Bruce Rowsell (Health and Welfare Canada); Jeff Poston (Canadian Pharmaceutical Association); Wayne Schnarr (the Canadian Drug Manufacturers Association); Alan Strong (Ayerst Laboratories); Jake Thiessen (University of Toronto); Pierre L. Guertin (Conseil consultatif de pharmacologie, Québec); Jack Williams (formerly of the Pharmaceutical Inquiry of Ontario); and William Wensley (formerly of the Ontario College of Pharmacists).

A study that examines drug reimbursement programs at the provincial level needs good, reliable, highly disaggregated data, and also assistance and advice on interpreting the data. The author was fortunate that the provinces studied here were generous with both.

Participants in seminars at the Economic Council, Statistics Canada, and the Annual Meetings of the Canadian Economics Association made useful suggestions. Three anonymous readers provided valuable criticisms of the original manuscript. At the Economic Council, the Text Processing Centre provided prompt and efficient word processing for the entire study, often under tight deadlines, and Francesca Worrall did a superb editing job. Finally, my appreciation goes to Judith Maxwell and Caroline Pestieau of the Economic Council, and Wendy Kennedy and Jack Williams of the Pharmaceutical Inquiry of Ontario for giving me the opportunity to work on this study in its various incarnations.

The usual disclaimer applies.

Foreword

This study has been published by the Economic Council of Canada, with the support of the Ontario Ministry of Health. It was initiated as background research for the Pharmaceutical Inquiry of Ontario and has been extensively revised, not only to cover a number of additional topics, but also to provide a more Canada-wide perspective.

The study raises a broad range of issues concerning the management of drug programs, from the merits of alternative forms of user charges and the appropriate mechanism for setting the pharmacist's dispensing fee, to the virtues of different drug pricing systems. Insights into the behaviour and motivation of pharmacists, physicians, generic and brand-name drug firms, and consumers are drawn upon in discussing these issues. Irrespective of whether the study's preferred options are implemented, it will enable a greater appreciation and understanding of the forces that help to shape provincial drug programs. As such, it will foster constructive dialogue and improved policy making.

Effective and efficient program management and delivery are of paramount importance at the present time. Health-care budgets have expanded rapidly, and drugs are no exception. Indeed, their rate of growth has exceeded that of the overall health-care budget. At the same time, governments are faced with fiscal restraint.

Dr. Gorecki has published extensively on the subject of drug programs. His expertise has been sought by a number of commissions (including the federal Commission of Inquiry on the Pharmaceutical Industry) and the Attorney General of Canada in the case of *Smith Kline and French Laboratories Limited et al. vs. the Attorney General of Canada*. More recently, he presented briefs to the House of Commons and Senate committees on Bill C-22, which amended the Patent Act.

Michael Decter
Deputy Minister
Ontario Ministry of Health

Judith Maxwell
Chairman
Economic Council of Canada

READER'S NOTE

The reader should note that various conventional symbols similar to those used by Statistics Canada have been used in the tables:

. .	figures not available
. . .	figures not appropriate or not applicable
– –	amount too small to be expressed
–	nil or zero.

Details may not add up to totals because of rounding.

1 Introduction

In the post-World War II prosperity of the 1950s and 1960s, many Organisation for Economic Co-operation and Development (OECD) countries intervened in the health-care sector to provide wider, if not universal, access to care of high quality. Partly as a result of the creation of these financial and delivery systems, but also because of demographic and technological developments, health-care expenditure grew rapidly. In the seven major OECD countries it increased as a percentage of the gross national product (GNP) from an average of 4.4 per cent in 1960 to 7 per cent in 1975, and the ratio of public to total health expenditure increased from 60.3 to 74.3 per cent.[1]

Although the increase in health-care expenditure slowed down between the mid-1970s to the mid-1980s, it nevertheless accounted for an average of 8 per cent of the GNP of the seven major OECD countries in 1984 [Schieber 1987, Table 18, 55]. This increase, combined with recession and stagflation across many OECD countries, put considerable strain on governmental financial resources. Even with the sustained growth of the mid-to-late 1980s, this strain continued because of the size of the cumulated debt that required servicing. Not surprisingly, given these conditions, public expenditure on health care has come under close examination in many OECD countries. Attention was focused on topics such as resource allocation, the efficiency and effectiveness of public administration, and the appropriate balance between the public and private sectors. Access and delivery systems had to share the health-care agenda with these new issues.

These changes in the health-care policy agenda resulted in problems because health-care systems had developed in response to a different set of issues. This quandary is set out as follows in a recent OECD study on the financing and delivery of health care:

> It has become increasingly clear that health care financing and delivery systems that were initially designed to assure access and promote the capacity of delivery systems were not well suited to the achievement of efficiency in either the provision or use of services. Indeed there is near-universal consensus that there are substantial allocative inefficiencies in the provision and use of health services, and that there is substantial excess capacity in terms of both manpower and facilities [Schieber 1987, 2].

If this view is correct, then health-care costs can be reduced and the same level of services provided, or, for the resources presently consumed, a higher level of services can be provided.

Canada is no exception to this characterization of OECD countries' health-care issues.[2] Health-care expenditure in Canada increased from 5.5 per cent of GNP in 1960 to 7.2 per cent in 1970; public expenditure as a proportion of total expenditure on health care increased from 43.1 to 70.2 per cent in the same period [Schieber 1987, Table 18, 55]. However, over the 1970s, after the establishment of the national medical insurance program in 1971, health expenditure as a proportion of GNP stayed between 7 and 7.5 per cent, before increasing in the 1980s to reach 8.9 per cent in 1989 [Canada Department of Health and Welfare 1990, Table 1, 27; United States General Accounting Office 1991, 5].

In contrast, the United States, which did not introduce a national medical insurance system, saw health-care expenditure increase from a level much the same as Canada's in 1970, to 9.1 per cent in 1980, and 11.6 per cent in 1989 [Canada Department of Health and Welfare 1990, Table 85, 136; United States General Accounting Office 1991, 5]. A major reason for the differential growth rates between the two countries was that Canada's universal public system permitted control to be exercised over the main spending channels – physician services, hospitals, and administration – in a way that was not possible in the largely privately funded, fragmented U.S. health system [United States General Accounting Office 1991; R. W. Evans 1983*a*, 1983*b*; R. G. Evans 1990].

Now, in a period of fiscal restraint, governments in Canada are concerned about the rise in health-care costs. A number of federal and provincial inquiries[3] have addressed the problem of how these costs can be contained while at the same time preserving portability, universality, comprehensiveness, and accessibility for all Canadians to high-quality health services.[4] Innovative payment and incentive systems, administrative reforms, controls on the number of health professionals, much greater emphasis on outcomes, and more efficient allocation of health-care resources are all possible solutions to the problem. Some measures have been taken, perhaps the most visible being

the elimination of physicians' right to charge patients more than the agreed upon provincial fee schedule, known as extra billing, with the passage of the Canada Health Act in 1984. This issue garnered front page headlines as confrontations with doctors developed in implementing the policy.

One of the causes of rising health-care costs is the general problem of the "greying" of society. A change is occurring in Canada's age structure such that the proportion of those aged 65 and over is increasing[5] – one forecast predicts that it is likely to double within 50 years.[6] This demographic change will increase expenditure, given the higher demand among the elderly for health-care services. Canadians will thus have to carefully shepherd and manage their resources in order to satisfy these requirements.

Drugs and Health-Care Costs

This study examines one part of health-care expenditure – drugs, and particularly prescribed drugs. Although prescribed drugs accounted for only 5.9 per cent of all health expenditure in 1987, they are one of the components of health-care expenditure that has increased most rapidly in recent times. For example, over the period 1975-87, total Canadian health expenditure (measured in 1981 dollars) increased by 83.4 per cent, while expenditure on prescribed drugs rose by 128.9 per cent [Canada Department of Health and Welfare 1990, Table 12, 38]. This rapid rise has led, at least in the publicly funded drug programs, to the introduction of measures such as patient/consumer copayment and restrictions of eligible benefits in order to reduce public, if not necessarily societal, expenditure on drugs.

Provincial Drug Expenditure

The level of, and growth in, expenditure on drugs has not been uniform across the provinces, for a number of reasons. In order to control for one of the more obvious reasons – the size of the provincial population – the total public and private real per-capita expenditure on drugs in 1975, 1980, 1985, and 1987 in Canada and the provinces was estimated (Table 1-1).

Between 1975 and 1987 Canada-wide per-capita expenditure on drugs doubled, increasing from $42.07 to $85.32. There was a considerable variation in per-capita growth rates among the provinces. In Nova Scotia it quadrupled, while increases of less than one quarter were recorded for both Prince Edward Island and Saskatchewan. The net result of these widely differing growth rates was an increase in the difference between the provinces with the highest and the lowest per-capita expenditure: in 1975 the ratio of the lowest to the highest was 1.55; by 1987 it had increased to 3.68, very large variations. One of the issues addressed in this study is why these disparities occurred, with reference to provincial drug reimbursement programs.

Table 1-1

Public and private per-capita expenditure on prescription drugs,[1] Canada and the provinces, selected years, 1975-87

	1975	1980	1985	1987	Ratio 1987/1975
	(1981 dollars)[2]				
British Columbia	45.57	60.71	60.42	64.62	1.42
Alberta	41.38	44.12	62.51	70.63	1.71
Saskatchewan	50.73	41.72	59.07	62.75	1.24
Manitoba	36.30	41.43	55.05	59.51	1.64
Ontario	48.60	56.03	89.22	109.41	2.25
Quebec	33.84	30.31	52.06	64.29	1.90
New Brunswick	32.75	58.99	82.16	106.03	3.24
Nova Scotia	40.27	65.59	113.10	166.90	4.14
Prince Edward Island	38.05	43.33	51.95	45.03	1.18
Newfoundland	36.66	70.17	58.86	56.31	1.54
Canada	42.07	48.08	70.78	85.32	2.03

1 Includes dispensing fee.
2 Expenditure deflated by the gross domestic product deflator.
Source: Canada Department of Health and Welfare [1990].

The Changing Balance: Private and Public Drug Expenditure

The share of overall health expenditure accounted for by the public sector increased in the 1960s and then stabilized at around 74 to 76 per cent from the early 1970s. In contrast, the increase in the share of drug expenditure accounted for by the public sector started in the mid-1970s and was not of the same magnitude (Figure 1-1). This lag reflects the establishment, or extension to major new user groups, of provincial drug programs in the 1970s.

The shift in responsibility for drug expenditure from the private sector to the public sector is reflected in the changing importance of drug expenditure in public and private health expenditure. Between 1970 and 1987, drugs increased as a proportion of public health-care expenditure from less than 0.5 to 4.01 per cent and decreased as a proportion of all private health-care expenditure from 19 to 11.3 per cent (Figure 1-2). Thus, although the funding of drugs is shifting from the private to the public sector, expenditure on drugs is still proportionately higher in the private than the public sector.

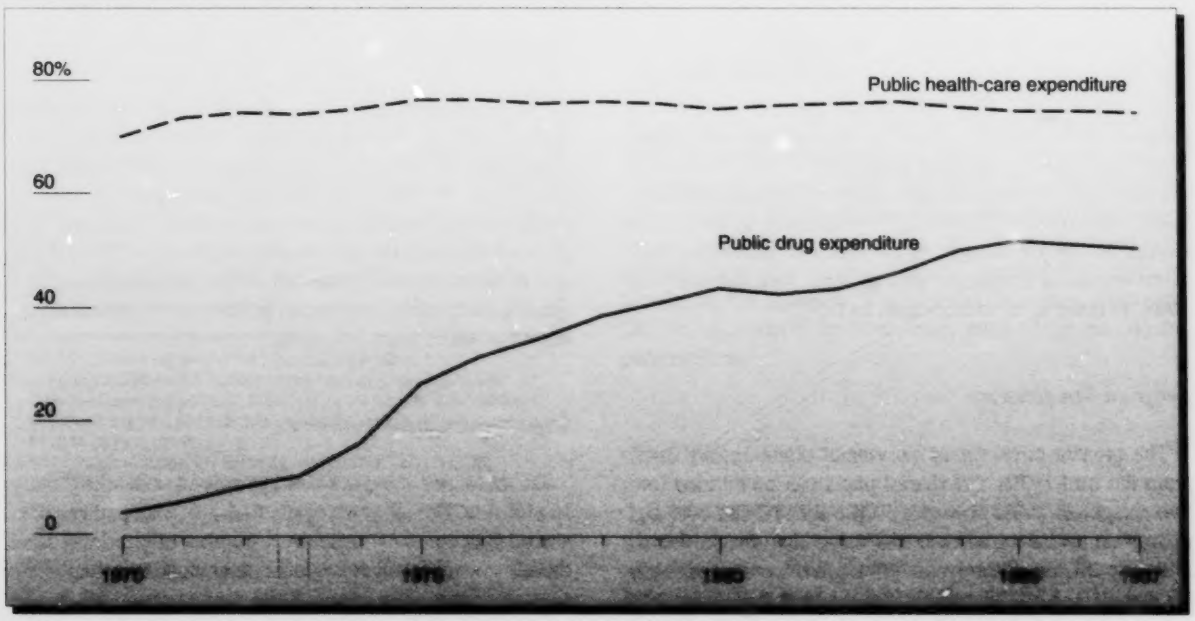
At the provincial level, like at the national level, there was a general upward trend in the importance of the public sector in accounting for total drug expenditure from 1975 (Table 1-2). However, there is considerable variation across provinces, reflecting not only the different groups covered by provincial drug plans, but also patient/consumer copayments and the characteristics of the populations.

Provincial Drug Programs: A Thumbnail Sketch

In this study, rather than examining cost-control mechanisms in each province, which would require detailed institutional knowledge and access to good data, one province – Ontario – was selected. This province is arguably the most important, not only because its market is the largest in Canada, accounting for 46 per cent of all drug expenditure in 1987, but also because its policies affect and are followed in other jurisdictions. Thus mistakes or successes in Ontario have the potential to influence all of Canada. Extensive reference will also be made to the experiences of other provinces, since in several important areas they provide useful lessons for Ontario.

Figure 1-1

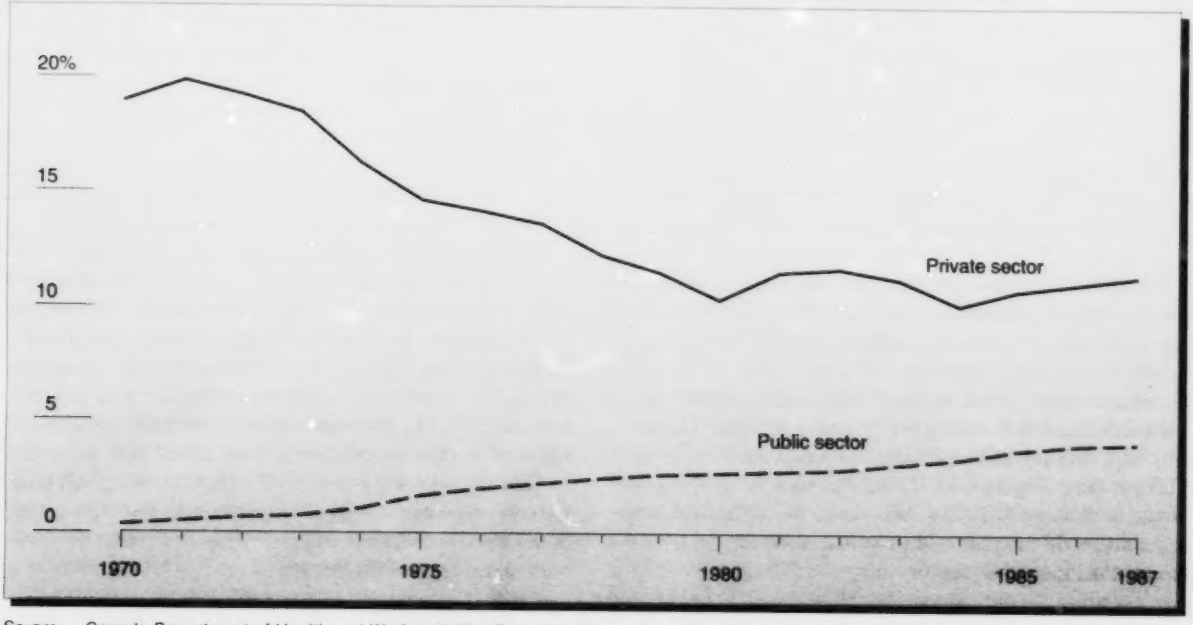
Public health-care expenditure as a proportion of total health-care expenditure, and public expenditure on drugs as a proportion of total expenditure on drugs, Canada, 1970-87



SOURCE Canada Department of Health and Welfare [1984, Table 56, 86, and Table 58, 88; 1990, Table 69, 96-97]; and special tabulations, Health Information Division, Department of Health and Welfare.

Figure 1-2

Prescribed drugs as a proportion of public and private health expenditure, Canada, 1970-87



SOURCE: Canada Department of Health and Welfare [1984, Table 56, 86, and Table 58, 88]; and special tabulations, Health Information Division, Department of Health and Welfare.

A brief overview of the major features of the 10 provincial drug reimbursement programs will place Ontario in a wider context and also demonstrate the relevance of the experience of other provinces to Ontario and vice versa. Describing provincial drug programs is a difficult task, because each plan has a large number of idiosyncrasies and each has evolved differently. Nevertheless, given this caveat, the major features of Canada's 10 provincial drug reimbursement programs will be described for the year 1989, in some instances updated to 1991.[7]

Program Beneficiaries

The present coverage of provincial plans largely dates from the mid-1970s. Provincial plans can be divided into two categories: those covering people aged 65 and over and people on social assistance; and those that are universal, covering all, or virtually all, of a province's population (Figure 1-3). Most plans fall into the first category, with private plans providing coverage for the majority of the balance of the population. Only British Columbia, Manitoba, and Saskatchewan provide universal coverage.

Program Benefits

Provincial drug plans typically allow, as benefits, all or virtually all prescribed drugs and some over-the-counter medicines. A number of provinces reduced the range of benefits in the 1980s by delisting some over-the-counter medicines and restricting access to certain high-cost new prescribed drugs. (In Alberta this occurred in 1991.) There are, however, some differences in the benefits offered and the degree to which provincial governments control access to newer, more expensive drugs.

Copayment: Extent and Form

Direct or user charges are not permitted under the Canada Health Act. This does not apply to drugs, except those consumed in acute-care hospitals. A number of provinces have therefore introduced copayment mechanisms, under which some or all program beneficiaries pay a portion of the cost of their prescriptions. Frequently, these mechanisms were introduced as a result of the financial exigencies referred to above. Indeed, in 1989, all but three provinces – Ontario,

Table 1-2

Public-sector expenditure as a proportion of total expenditure on prescription drugs,[1] Canada and the provinces, selected years, 1975-87

	1975	1980	1985	1987
		(Per cent)		
British Columbia	35.2	37.6	65.8	66.7
Alberta	27.8	31.7	41.4	45.7
Saskatchewan	32.7	76.2	99.3	86.7
Manitoba	28.7	37.1	55.5	54.5
Ontario	16.5	36.1	43.1	42.5
Quebec	35.5	73.8	63.5	62.8
New Brunswick	35.6	40.7	50.7	44.8
Nova Scotia	38.0	36.9	40.4	34.2
Prince Edward Island	33.3	24.5	31.6	56.8
Newfoundland	31.1	22.6	48.8	66.5
Canada	26.5	43.4	51.6	50.5

1 Includes dispensing fee.
Source Special tabulations, Health Information Division, Department of Health and Welfare.

Figure 1-3

Coverage and copayment under provincial drug reimbursement programs, 1989

	Copayment	
	Yes[1]	No
Coverage:		
Persons aged 65 and over or on social assistance[2]	Alberta, New Brunswick, Newfoundland, Prince Edward Island	Ontario, Quebec, Nova Scotia
Universal	British Columbia, Manitoba, Saskatchewan	...

1 For one or more subsets of the population identified.
2 In some instances also includes home care, long-term care, and disease-related groups (e.g., diabetics). In the case of Newfoundland, only those aged 65 and over and receiving the Guaranteed Income Supplement are covered.
Source Pharmaceutical Inquiry of Ontario [1990a, Table 3.3, 30].

Nova Scotia, and Quebec – had some form of copayment (Figure 1-3).[8]

Copayments differ considerably by province. Furthermore, even within a province, different beneficiary groups may have different copayments, with those on social assistance usually having no copayment. In view of this intraprovincial variation, we only examined copayment mechanisms for those aged 65 and over (Figure 1-4). This group, however, accounts for a substantial share of provincial drug expenditure and is included under all provincial plans.

Five different copayment mechanisms were identified. These vary from the beneficiary paying a percentage of the dispensing fee – 75 per cent in British Columbia and 100 per cent in Newfoundland, but only up to an annual cumulative maximum dollar amount in the case of British Columbia – to the beneficiary paying all prescription costs up to a cumulative annual dollar total, after which the beneficiary pays only a portion of the prescription price. In Manitoba, for a family, the cumulative annual total was $88.50, after which the beneficiary paid 20 per cent of the prescription.

Dispensing Fee

In most provinces the pharmacists' dispensing fee is negotiated between the government and the provincial pharmacy association. In British Columbia, however, the fee is set in the marketplace, with each pharmacy setting its own fee. In 1989, dispensing fees across the provinces were in the range of $5.90 to $6.60. There were two outliers, however – in Quebec, the fee was $4.70 for the first 20,000 prescriptions

Figure 1-4

Provincial drug reimbursement programs: copayment mechanisms, persons aged 65 and over,[1] 1989

Copayment mechanism:	Province
None	Ontario, Quebec, Nova Scotia
Percentage of dispensing fee	British Columbia,[2] Newfoundland[3]
Percentage of prescription price[4]	Alberta[5]
Fixed dollar per prescription	New Brunswick[6]
Dispensing fee plus part of drug cost	Prince Edward Island[7]
All prescription costs up to a cumulative annual total, plus a percentage of each prescription[4] thereafter	Manitoba,[8] Saskatchewan[9]

1 Not all the beneficiary groups have the same copayment mechanism; therefore those persons aged 65 and over were selected.
2 75 per cent of the fee, up to a cumulative annual maximum of $125.
3 100 per cent of the fee, no cumulative annual maximum.
4 Prescription price includes dispensing fee and drug cost.
5 20 per cent of the price, no cumulative annual maximum.
6 $6.34 per prescription. For those aged 65 and over *and* receiving the Guaranteed Income Supplement, there is a cumulative maximum copayment of $120.
7 $4, no cumulative annual maximum.
8 $88.50 per family, plus 20 per cent of prescription thereafter.
9 $75 per family, $50 per single person, plus 20 per cent of prescription price thereafter.

SOURCE Pharmaceutical Inquiry of Ontario [1990a, Table 3.3, 30].

Figure 1-5

Provincial drug reimbursement programs: models for setting drug prices, 1989

Model:	Province
Actual acquisition cost[1]	British Columbia, New Brunswick, Nova Scotia
Standing offer contracts[2]	Saskatchewan
Best available price[3]	Ontario, Quebec, Newfoundland, Manitoba
Miscellaneous[4]	Alberta, Prince Edward Island

1 Pharmacists bill the government the actual acquisition cost of the drug, net of discounts, rebates, and so on. They are usually allowed to select a lower-priced interchangeable brand than that prescribed. In Nova Scotia and New Brunswick, interchangeable brands are listed in a formulary.
2 For high-volume interchangeable drugs, brand choice is made on the basis of a semi-annual tender or auction, under which, other things being equal, the low bidder is awarded a six-month contract to supply Saskatchewan's needs for that drug. For non-SOC drugs, the AAC model is used.
3 The provincial government sets a price for each brand – based on manufacturers' prices – which is published in a formulary. An attempt is usually made to take into account any volume buying discounts, particularly for high-volume drugs. Where there are several interchangeable brands, the government will only reimburse up to the lowest-priced brand (Ontario, Manitoba, and Newfoundland) or the median (Quebec) irrespective of which brand is actually dispensed. In Manitoba and Newfoundland, the formulary only contains interchangeable drugs. In both provinces, for those drugs not listed that are benefits, the drug plan will typically pay a price based on the smallest package-size. The best available price refers to the Ontario variant of this approach to drug reimbursement.
4 In setting the price at which it reimburses the pharmacist, the province makes some attempt to take into account buying economies on selected drugs. There was no product selection legislation in Prince Edward Island, while in Alberta this was at the discretion of the pharmacist. Neither province had an interchangeable drug listing.

SOURCE Anderson [1989]; Canadian Pharmaceutical Association [1989]; and discussions with provincial government officials.

dispensed by a pharmacy and $4.05 thereafter; and in Nova Scotia it was $7.53.

Drug Pricing

In 1989, four different models were used by provincial governments to determine drug prices (Figure 1-5). These vary in terms of the price determination of an individual brand and an interchangeable drug (where there are several therapeutically equivalent brands of the same drug with varying prices). The models fall along a spectrum. At one end is the actual-acquisition-cost (AAC) model, under which decisions as to brand choice and price are, to a great extent, the responsibility of the pharmacist. At the other is the standing-offer-contract (SOC) model, under which the provincial government determines both brand choice and price on the basis of competitive tendering. The AAC model applies to single-source and interchangeable drugs, and the SOC model is confined to high-dollar-volume interchangeable drugs. In Saskatchewan, the AAC model was used for non-SOC drugs.

The best-available-price (BAP) model is used in Ontario, with variants in Quebec, Manitoba, and Newfoundland. However, by 1991 Nova Scotia, New Brunswick, and Prince Edward Island had also adopted variants of it, making it the most widely used in Canada. Recently, the British Columbia Royal Commission on Health Care and Costs [1991, vol. 2, C-128] recommended that a BAP-type system be implemented in that province. Under this system

the government sets brand prices and reimburses for no more than those prices. In the case of interchangeable drugs, the maximum price paid by the provincial plan is that of the lowest-priced brand, except in Quebec where the median price is selected. The pharmacist determines, however, which interchangeable brand to dispense at that price.

In the case of the "miscellaneous" model, some attempt is made to take into account buying economies for certain drug products. In the case of interchangeable drugs, there is little incentive for the pharmacist to product select. Indeed, there was no product selection legislation in Prince Edward Island until 1991. Since 1989, both Prince Edward Island and Alberta have moved away from the "miscellaneous" model – Prince Edward Island to a BAP variant, and Alberta to the AAC model.

Why Have Drug Program Costs Risen: A Top-Down Approach

This study makes extensive interprovincial and intraprovincial comparisons between drug pricing systems, mechanisms for determining dispensing fees, and so on. These comparisons are frequently made at quite a fine level of detail, such as the individual brand of a given drug. On the basis of this detailed analysis and some a priori reasoning, we also discuss policy options.

A top-down approach that decomposes provincial per-capita drug expenditure into components reflecting drug cost, dispensing fee, number of claims, and so on will provide an indication of the importance of the factors selected for examination in this study. It will also provide valuable information on the reasons why some provinces spend much less per capita than others.

An equation consistent with this top-down approach is:

$$DRGCAP = \sum_{i=1}^{N} B_i (\propto_i \bar{q}_i^* (dc_i^* + df_i^*)) \qquad (1.1)$$

where

$DRGCAP$ = the per-capita drug plan expenditure;
N = the number of age groups;
B_i = the share of the eligible population accounted for by the i^{th} age group;
$\propto_i$ = the proportion of the eligible population in the i^{th} age group for which at least one claim is made;
$\bar{q}_i^*$ = the average number of monthly equivalent claims, per beneficiary, i^{th} age group;
dc_i^* = the drug cost per monthly equivalent claim, i^{th} age group; and
df_i^* = the dispensing fee per monthly equivalent claim, i^{th} age group.

Monthly equivalents reflect the fact that a course of treatment longer than a month may result in one or more separate claims, depending on whether the medication is dispensed on one or several prescriptions.

Unfortunately the data are not available to estimate equation 1.1 for individual provinces. Fragments are, however, available, such as $\propto$ by age group for those covered by the Saskatchewan and Quebec provincial drug plans. Furthermore, valid comparisons can be made through time within a province, using actual drug cost, dispensing fees, and number of claims, providing that the number of claims per given course of treatment does not vary or varies in a known manner. In Chapter 2, this exercise is conducted with a view to identifying those factors that have been responsible for the rise in expenditure between 1979/80 and 1988/89 under Ontario's drug plan.

Nevertheless, this falls well short of the sort of interprovincial comparisons envisaged using equation 1.1. This can be partially rectified by the following equation, based on equation 1.1:

$$DRGCAP_N = \propto_N \bar{q}_N (dc_N + df_N) \qquad (1.2)$$

where N refers to those aged 65 and over, while $\bar{q}$, dc, and df refer to actual, rather than monthly, equivalents, and df and dc include any beneficiary copayment.

All of the arguments in equation 1.2 are presented in Table 1-3 for British Columbia, Saskatchewan, Ontario, and Quebec for 1987. British Columbia and Saskatchewan have much the same level of per-capita expenditure, while Quebec and particularly Ontario have much higher levels of expenditure. (This is broadly consistent with Table 1-1, which includes all age groups and total drug expenditure.)

There are some startling differences and similarities. Perhaps the most striking difference is in the number of claims per active beneficiary, with Ontario and Quebec far exceeding British Columbia and to a lesser extent Saskatchewan. One cannot, however, infer from this that senior citizens in British Columbia consume fewer drugs than those in the other three provinces. This is because in British Columbia the average claim is for a longer course of treatment than in the other three provinces. While in the other provinces it is in the vicinity of a month, in British Columbia it is perhaps 50 per cent longer. Even taking this into account,

Table 1-3

Drug costs, dispensing fees, and number of claims for persons aged 65 and over, selected provincial drug reimbursement programs, 1987

	$\propto$	$\bar{q}$	dc	df	*DRGCAP*
	(Proportion)	(Number)		(Dollars)	
British Columbia	0.895	13.5	12.33	6.06	222.19
Saskatchewan[1]	0.864	18.4	11.73	5.14	268.12
Ontario[2]	0.920	28.6	10.96	5.12	422.82
Quebec	0.861	28.5	9.90	4.33	349.38

$\propto$ = the proportion of the eligible population for which at least one claim is made;
$\bar{q}$ = the average number of claims per beneficiary;
dc = the drug cost per claim, including any beneficiary copayment;
df = the dispensing fee per claim, including any beneficiary copayment; and
DRGCAP = the per-capita expenditure on drugs and dispensing fees, all eligible beneficiaries aged 65 and over.
1 Fiscal year ending 31 March 1987.
2 Fiscal year ending 31 March 1988.
Source: Bureau of Pharmaceutical Surveillance, Department of Health and Welfare; and Saskatchewan Health Prescription Drug Plan [1987, Table X, 23].

however, a substantial difference remains between, on the one hand, Ontario and Quebec and, on the other, British Columbia and Saskatchewan. These differences may reflect different provincial attitudes to prescribing drugs, the number of physicians in the province, the health of the population, the climate, the fact that British Columbia and Saskatchewan conduct drug utilization reviews, and Ontario and Quebec do not, and the range of benefits offered by the provincial drug plans.

The differences in drug costs are less marked. The higher cost in British Columbia may reflect the fact that each claim is for a longer period of time, so more of a drug is dispensed per claim and each claim is thus more expensive. Finally, dispensing fees vary considerably. Quebec seems to be successfully keeping its fees down, and British Columbia's higher fees may be misleading because each prescription covers a longer course of treatment.

The major factor that seems to account for interprovincial differences in drug expenditure is the number of claims – at least between the two high-cost provinces and the two low-cost provinces. But aggregate interprovincial comparisons such as those in Table 1-3, even when they standardize for age, seem to raise as many questions as they settle. Many of the issues they raise can only be resolved by studying the issues in microdetail, which much of this study attempts to do.

2 Problems, Causes, Solutions, and Choices

The objectives of the publicly funded drug program in Ontario, the Ontario Drug Benefit (ODB), and the problems it faces are a microcosm of those that confront health care in general. The motivation for intervention in the 1970s was to provide drugs to certain groups, "with the intent of alleviating the financial burden of drug therapy" [Ontario Ministry of Health 1988*e*]. In the 1980s, however, the government became concerned about the rising overall cost of the program as well as the quality of prescribing. In this chapter, the background, magnitude, and causes of the rising costs are sketched and possible solutions presented. There are a large number of potential solutions; in order to discriminate between them the various criteria are outlined.

The Issues

Since 1974-76, the Ontario Drug Benefit program has provided prescription and some over-the-counter (OTC) drugs free to senior citizens, those on social assistance, and a number of smaller groups. These costs have risen substantially – from $44 million in 1975/76 to $916 million in 1990/91 [Ontario Ministry of Treasury and Economics 1991, 12]. Not only is this a large absolute amount, but the ODB is among the fastest growing provincial government health programs in Ontario; its share of provincial health-care expenditure increased from 2.7 to 4.9 per cent between 1981 and 1991 [Ontario Ministry of Treasury and Economics 1991, 4].

The future seems to hold out little prospect that drug expenditure, either in general or under the ODB, will fall. On the demand side, the numbers of the heaviest users of drugs, those aged 65 and over, are expected to increase substantially between 1986 and 1996 from 10.9 to 13.2 per cent of the province's population [Ontario Ministry of Health 1988*b*, 17]. On the supply side, there is concern over the high price of new drugs, especially in view of the introduction in 1987 of a seven-to-ten-year delay before a compulsory patent licence can be granted [Gorecki 1987*b*; Shulman and Richard 1988] and the increasingly oligopolistic nature of the drug industry.[1] These developments may, of course, be offset by the federal Patented Medicine Prices Review Board, which was created in 1987 and charged with ensuring that the prices of patented drugs are not excessive [Patented Medicine Prices Review Board 1989, 1991; Shulman and Richard 1988].

Furthermore, the federal government's share of Ontario's health and postsecondary education expenditure has fallen by over 15 percentage points during the past decade: from a couple of percentage points above 50 per cent in 1979/80 to a percentage point or so below 35 per cent in 1990/91 [Nixon 1990, 11]. In other words, in 1990/91, Ontario will be spending 65 cents on the dollar on health and postsecondary education rather than 50 cents. This provides an added incentive for careful management of the ODB.

The concern over increased ODB costs is part of a much wider anxiety that the consumption of drugs is too high because inappropriate as well as ineffective drugs are being prescribed, and that dangerous combinations are possibly being taken by patients. Nevertheless, these concerns should not obscure the fact that drugs make important contributions to extending life and improving its quality [Brown and Luce 1990; Brown et al. 1991].

The issues of costs and benefits are, of course, related. Indeed, they are probably complementary. If Ontarians are indeed consuming too many and/or too expensive drugs, then appropriate measures to correct this situation should lead to a reduced demand for drugs. In order to do this, the incentives and measures introduced with respect to the cost and benefit issues must be mutually reinforcing rather than offsetting each other or working at cross-purposes.

The Causes

There are numerous reasons why ODB expenditure has increased. In this section we consider the size of the eligible population; the proportion that claim under the program; the cost of drugs; the dispensing fee; and the number of claims per beneficiary for the period 1979/80 to 1988/89. The period was selected because there were no addition to the groups eligible for benefits; there may, however, have been changes in their composition as those on welfare increased in bad times and decreased in good times.

Total Expenditure

Total expenditure under the ODB may be written as:

$$TE = q \cdot p \qquad (2.1)$$

where

TE = total expenditure;
q = quantity, measured as the total number of claims; and
p = price, measured as the average cost per claim.

Furthermore, p can be broken down into two components, the dispensing fee and drug cost. Substituting into equation 2.1 yields

$$TE = q \cdot (dc + df) \qquad (2.2)$$

where

dc = the drug cost per claim; and
df = the dispensing fee per claim.

Thus total expenditure can rise because any of the three arguments in equation 2.2 increase.

In Table 2-1, the components of equation 2.2 are presented for the period 1979/80 to 1987/88. The data are presented in index form, with 1979/80 set equal to 100 for each of the three components of equation 2.2. Since drug costs and dispensing fees are in nominal dollars, the consumer price index is also included. The real or inflation-adjusted increase in the drug cost and the dispensing fee is estimated by deflating the nominal figures by the consumer price index. It is this adjusted number that has to be compared with quantity in evaluating changes in q, dc, and df in equation 2.2.

Over the period 1979/80 to 1987/88, the number of claims or quantity was the fastest growing item, virtually doubling. A claim is a separate billing to the ODB by a pharmacist for dispensing a drug to a patient/consumer. It thus consists of the dispensing fee and the drug cost. It is not necessarily synonymous with the number of prescriptions. The number of claims is likely to be larger because for much of the history of the ODB pharmacists could make a separate claim for each month's supply of a drug. Thus if a prescription was for a 90-day supply, this could result in three separate monthly claims. In real terms then, the most important factor causing total ODB expenditure to rise was the number of claims or quantity.

The second fastest growing item was the drug cost, which increased in real terms by more than half. Some claim that one reason for this increase is that the newer drugs coming onto the market have much higher introductory or entry-level prices.[2] As one group has commented:

> Examples of just a few are: the drug AZT, used in the treatment of AIDS at approximately $1,000 per month per patient; Tegison at $72 per 36 tablets; Corderone [sic] at $150 per 100 tablets and Pepcid at $137 per 100 tablets. Prior to these recent developments in Canada, we had never seen a prescription drug with an introductory price in excess of $1 per tablet [Canadian Drug Manufacturers Association 1988, 4].[3]

Table 2-1

Breakdown of expenditure on claims by the Ontario Drug Benefit, 1979/80 to 1987/88[1]

	Quantity (total number of claims)[2]	Drug cost (per claim)[3]	Dispensing fee (per claim)[4]	Consumer price index
1979/80	100.0	100.0	100.0	100.0
1980/81	108.9	121.1	106.3	110.9
1981/82	116.5	142.1	121.9	124.6
1982/83	129.1	173.7	134.4	136.7
1983/84	139.9	192.1	143.8	143.9
1984/85	151.3	202.6	156.3	149.6
1985/86	163.9	223.7	156.3	155.8
1986/87	179.1	242.1	165.6	162.2
1987/88[5]	193.7	265.8	184.4	169.2

1 Refers only to claims under the ODB with dispensing fees, approximately 90 per cent of total ODB expenditure in 1986/87. The remaining 10 per cent is over-the-counter drugs, flu vaccine, and oxygen.
2 In 1979/80 quantity, measured in terms of claims, was 15.8 million.
3 In 1979/80 drug cost per claim was $3.83 in current dollars.
4 In 1979/80 dispensing fee per claim was $3.15 in current dollars.
5 Estimate.
Source Ontario Ministry of Health [1988*b*, Appendix 3].

While the price per capsule or tablet may not be an altogether appropriate standard of comparison, in a much more thorough exercise for New Zealand, Sutton [1988] found that entry-level prices were substantially above the average cost of all medicines.

There is some indirect evidence to support this conclusion for Ontario. The average drug cost per ODB claim for single-source drug products – which would tend to be heavily weighted by newer drugs – increased from $6.33 in 1979/80 to $18.85 in 1987/88. The corresponding costs for interchangeable drug products – which would tend to be heavily weighted by older products – increased from $3.32 to $5.10.[4] Thus the cost of interchangeable drugs fell in real terms, while that of single-source drugs increased in real terms by 76 per cent. Of course, if the benefits are commensurate with the price increases, this is not necessarily an adverse development.

In contrast to quantity dispensed and price, the dispensing fee increased slightly in real terms. For several years the fee lagged behind inflation. This may, however, understate fee changes. For high-volume interchangeable drugs, the actual price paid by pharmacists was frequently below the price at which they were reimbursed by the government. This difference – the price-spread – accrued to the pharmacists. If this difference were reassigned from the drug cost to the dispensing fee, then the fee increases would be greater. Unfortunately, accurate data do not exist to readjust the fee for 1979/80 to 1987/88. As we shall see in Chapters 3 and 5, the price-spread has been substantial.

Quantity

Since quantity is the most important component in the rise in ODB expenditure, further analysis of the reasons for its rise was conducted. Quantity, in equation 2.2, can be broken down in the following way:

$$q = \propto \bullet Z\bar{q} \qquad (2.3)$$

where

$\propto$ = the proportion of the ODB eligible population for which at least one claim was made;
Z = the size of the eligible population; and
$\bar{q}$ = the average number of claims per beneficiary;

with $\propto$ varying between 0 and 1. Thus, q can increase either because (a) more of those eligible for ODB benefits claim them, (b) the eligible population increases, or (c) the demand among beneficiaries rises.

The ODB divides its eligible population into various plan types, depending on a number of factors, including the criteria used to select the group (e.g., age, income level), the length of time the benefits last, and where the drug is dispensed (e.g., pharmacy, institution). For some plan types there are reliable data on the plan's beneficiary and eligible populations (e.g., senior citizens), in others there are only data on the beneficiary and not the eligible population (e.g., those receiving family benefits),[5] while in still others the beneficiary and eligible populations appear to be the same.[6] A person may also qualify for benefits under more than one plan. For example, a person may be over 65 years of age and in institutional care. Thus the total eligible population for all plan types may involve some double counting. With these caveats in mind, attention can now be turned to examining the determinants of q.

Table 2-2 presents, in the last column, all the arguments of equation 2.3 for all the ODB plans taken together. This shows that $\propto$, Z, and $\bar{q}$ are all gradually increasing, particularly Z and $\bar{q}$. Over the period 1981/82 to 1988/89, the eligible population increased by 29 per cent, but the beneficiary population increased even more, so that $\propto$ increased from 0.89 to 0.96. In terms of future expenditure growth, with $\propto$ so close to unity, increases in the volume of claims will be due to a rise in the eligible population, its composition, and the number of claims per beneficiary.

Table 2-2 also breaks down $\propto$ and Z, but not $\bar{q}$, by ODB plan type. The most important group by far is seniors, accounting for 64.5 per cent of the ODB eligible population in 1988/89. In 1987/88 this group also accounted for approximately 80 per cent of ODB expenditure.[7] The $\propto$ of this group has increased from 0.88 to 0.94 in the period 1981/82 to 1988/89, but Z increased by nearly one quarter. One reason for the increase in $\propto$ is that the age structure of Ontario's population is changing, such that the average age of those aged 65 and over is increasing (Table 2-3) and the number of prescriptions consumed increases with age, as Table 2-4 clearly indicates for Saskatchewan and Figure 2-4 for Quebec (these data are unfortunately not readily available for Ontario).[8] Given these facts, ODB expenditure is likely to rise substantially in the next 10 to 20 years under the present policies.

Intensity of Care

The aging of Ontario's population, although an important factor, is not the only determinant of increases in ODB expenditure. A number of studies also point to other reasons, such as technology, which are considered to be as important, if not more so. R. G. Evans [1983*a*, 2], for example, states:

Table 2-2

Distribution of ODB eligible and beneficiary populations, by plan type, 1981/82 to 1988/89[1]

	Eligible persons					
	65 and over	Family benefits	General welfare	Home care	Other (institutional care)	All plan types
1981/82						
Z[2]	864,550	223,580	162,364	11,155	15,991	1,277,640
α[3]	0.88	0.81	1.00	1.00	1.00	0.89
$\bar{q}$[4]	..	..	..	..	..	18.8
1982/83						
Z	891,274	231,833	173,891	11,947	17,126	1,326,071
α	0.92	0.83	1.00	1.00	1.00	0.91
$\bar{q}$	..	..	..	..	..	19.3
1983/84						
Z	915,345	250,345	223,666	13,586	14,743	1,417,685
α	0.89	0.89	1.00	1.00	1.00	0.91
$\bar{q}$	..	..	..	..	..	19.5
1984/85						
Z	983,717	272,448	224,172	16,728	14,276	1,511,341
α	0.85	0.83	1.00	1.00	1.00	0.87
$\bar{q}$	..	..	..	..	..	20.7
1985/86						
Z	1,004,849	292,842	186,340	18,284	14,197	1,516,512
α	0.87	0.85	1.00	1.00	1.00	0.88
$\bar{q}$	..	..	..	..	..	22.4
1986/87						
Z	992,700	304,644	190,036	19,826	13,920	1,521,126
α	0.93	0.84	1.00	1.00	1.00	0.92
$\bar{q}$	..	..	..	..	..	24.0
1987/88						
Z	1,030,000	324,367	194,345	21,670	13,851	1,584,233
α	0.94	1.00	1.00	1.00	1.00	0.96
$\bar{q}$	..	..	..	..	..	22.5
1988/89						
Z	1,064,100	353,660	194,360	23,690	13,800	1,649,610
α	0.94	1.00	1.00	1.00	1.00	0.96
$\bar{q}$	..	..	..	..	..	22.9

1 The table refers to all claims whether for a prescription or over-the-counter medication.
2 Z = the size of the eligible population.
3 α = the proportion of the eligible population for which at least one claim was made.
4 $\bar{q}$ = average number of claims per beneficiary.
Source Ontario Ministry of Health, "Managing by results, results abstracts."

What *is* happening is that patterns of care for the elderly are shifting in response to changes in technology and in manpower and other resources in the health care system itself. Age-sex specific rates of utilization are rising faster for the elderly than for the general population. The "cost problem" is not that there are more elderly – though there are – but that the health care system is responding more intensively to what it defines as their "needs." The problem is in the health care system itself, not in external demographic forces.

Subsequent work by Grenier [1985] is consistent with this view.

Table 2-3

The age structure of the population, Ontario, 1986 and 1996 (projected)

	Age group					
	0-19	20-64	65-74	75-84	85 and over	All
			(Thousands)			
1986	2,559	5,550	603	303	87	9,102
1996	2,569	6,076	765	416	137	9,963
			(Per cent)			
Change	0.4	9.5	26.9	37.3	57.5	9.5

Source Ontario Ministry of Health [1988*b*, 17].

Table 2-4

Prescription drug utilization by age, Saskatchewan, 1986/87

				Number of prescriptions	
	Z[1] (1)	$\propto$[2] [(3)/(1)] (2)	$\propto Z$ (3)	q[3] (4)	$\bar{q}$[4] [(4)/(3)] (5)
Age group					
0-4	79,644	0.86	68,523	270,795	3.95
5-14	149,450	0.63	93,648	289,179	3.09
15-24	165,940	0.72	118,753	552,832	4.66
25-34	172,738	0.71	122,232	633,118	5.18
35-44	117,045	0.68	79,963	499,179	6.24
45-54	87,872	0.71	62,379	575,021	9.22
55-64	89,213	0.76	67,502	858,462	12.72
65-74	75,105	0.82	61,719	1,023,109	16.58
75-84	40,420	0.91	36,673	741,290	20.21
85 and over	12,485	0.97	12,171	271,972	22.35
Total	989,912	0.73	723,563	5,714,957	7.90

1 Z = the size of the eligible population.
2 $\propto$ = the proportion of the eligible population for which at least one claim was made (they are placed in an age group depending on their age when their most recent prescription was dispensed).
3 q = the total number of claims.
4 $\bar{q}$ = the average number of claims per beneficiary.
Source Saskatchewan Health Prescription Drug Plan [1987, Table III, 19].

In the above discussion of q, $\propto$ and $\bar{q}$ were not broken down by age. Instead, the implicit assumption was that q was increasing because Ontario's population has been aging – both $\propto$ and $\bar{q}$ rise with age. This is a widely held view. For example, 87.1 per cent of physicians in Ontario felt that the aging population was a very important factor leading to increased drug expenditure [Williams and Cockerill 1989, 50]. Statements such as those by Evans quoted above, however, raise the possibility that both $\propto$ and $\bar{q}$ are increasing for all age groups, but particularly the elderly. Thus greater intensity of care may not only be increasing expenditure on overall health care, but also ODB expenditure.

Unfortunately, there appears to be no readily available data on drug utilization by age for either Ontario or the ODB. Instead, to assess whether intensity of drug care has increased, we examined the Quebec and Saskatchewan

provincial drug programs. Quebec's provincial drug program is similar in size, coverage, and structure to Ontario's, while the Saskatchewan plan differs from both in that it provides universal coverage and is much smaller. Despite these differences, both show increases in $\propto$ and $\bar{q}$, holding age constant, through time.

Using the period 1983/84 to 1986/87, $\propto$ and $\bar{q}$ were estimated by age group for Saskatchewan (Figures 2-1 and 2-2). This period was chosen because a detailed breakdown for those aged 65 and over is available,[9] and there appeared to be no major change affecting the plan, such as a change in the criteria for determining eligibility. Although the period covered is only three years, there is an increase in both $\propto$ and $\bar{q}$ in all age groups, not just those groups over 65. The mean overall percentage increase in the number of claims per beneficiary, $\bar{q}$, was 9 per cent. However, all the age groups over 65 had increases above the average, varying between 11 and 13 per cent. Indeed, these three groups had the highest increases of all the age groups.[10]

In Quebec, $\propto$ and $\bar{q}$ for those aged 65 and over in 1983 and 1989 increased, holding age constant (Figure 2-3). While the increase in $\propto$ is about 3.6 percentage points or less, the number of prescriptions per beneficiary increased over the six-year period by 22.3 per cent for those aged 65-69, but by 45.3 per cent for those 75 or older (Figure 2-4). Thus it appears that what is true for overall health-care utilization patterns is also true of drugs – intensity of care is rising.

A Sense of Perspective

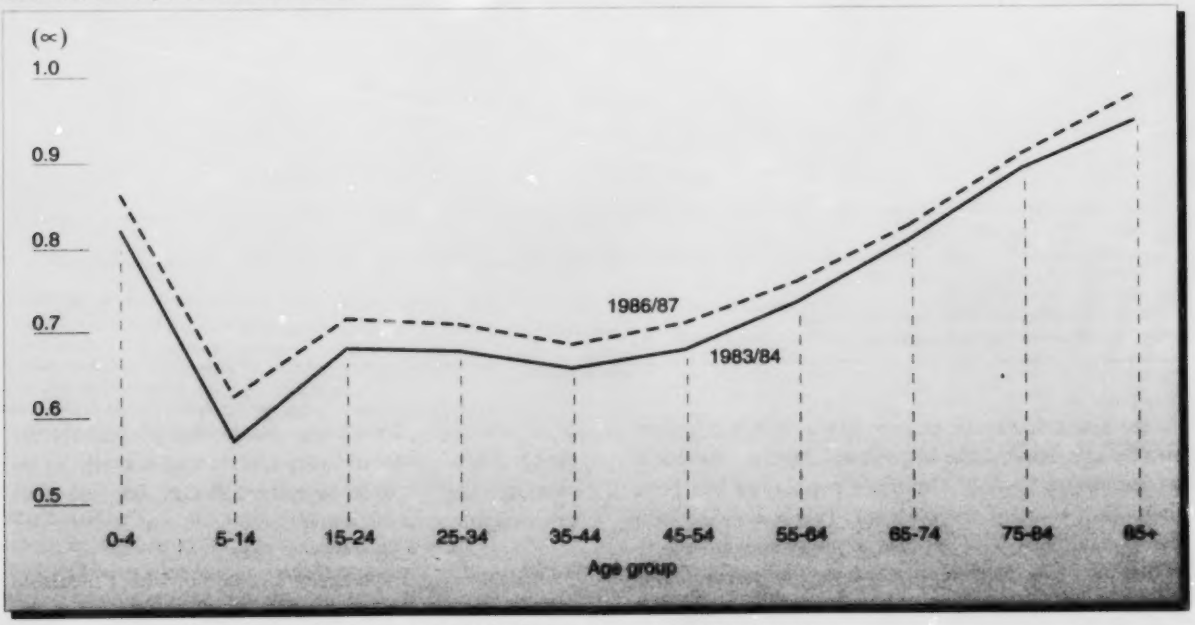
A number of factors have been suggested to account for the increase in ODB expenditure in the 1980s. In order to assess their relative importance, a simple, other things being equal, analysis was undertaken. Substituting equation 2.3 into equation 2.2 yields:

$$TE = \propto \bullet Z \bullet \bar{q} \bullet (dc + df).$$

In order to estimate the contribution of each argument to the increase in ODB expenditure over the period 1981/82 to 1987/88, the following procedure was followed.[11] *TE* was first estimated for 1981/82; then each argument was, in turn, allowed to take its 1987/88 value and *TE* re-estimated; this

Figure 2-1

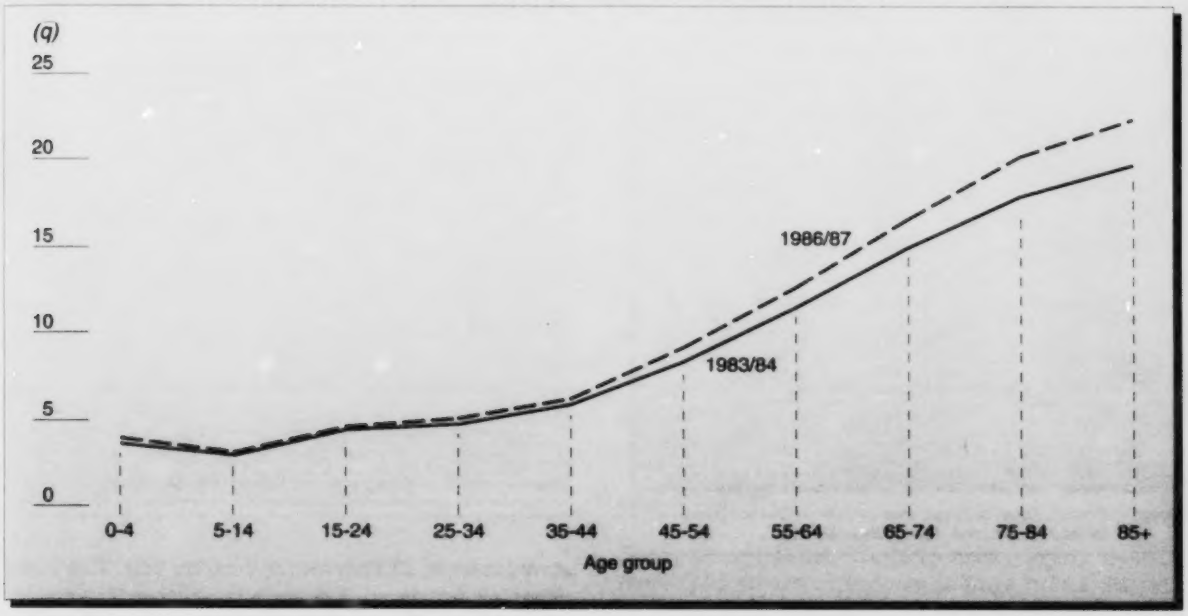
Proportion of the eligible population that are drug plan beneficiaries ($\propto$), by age group, Saskatchewan, 1983/84 and 1986/87



SOURCE Saskatchewan Health Prescription Drug Plan [1984, Table III, 17, and 1987, Table III, 19].

Figure 2-2

Average number of prescriptions per beneficiary *(q)*, by age group, Saskatchewan, 1983/84 and 1986/87



SOURCE Saskatchewan Health Prescription Drug Plan [1984, Table III, 17, and 1987, Table III, 19].

new value was compared with the actual 1981/82 *TE* value to derive how much expenditure would have increased had only that item changed between 1981/82 and 1987/88. All dollar figures were expressed in 1981/82 dollars.

Estimating the impact of the increased drug servicing of the population was somewhat more complex. The expected change in $\propto$ and $\bar{q}$, because of the aging of the population between 1981/82 and 1987/88, was first estimated.[12] The impact on the ODB of increased drug servicing of recipients is then the difference between *TE* derived from the 1981/82 values of Z, *dc*, and *df* and the 1987/88 values of $\propto$ and $\bar{q}$,[13] and *TE* derived from the 1981/82 values of Z, *dc*, and *df* and the expected 1987/88 value of $\propto$ and $\bar{q}$ due to the aging of the population.[14] The difference between these two values would be zero if no change took place in the number of claims per ODB recipient of a given age group, positive if the number of claims increased, and negative if it declined.

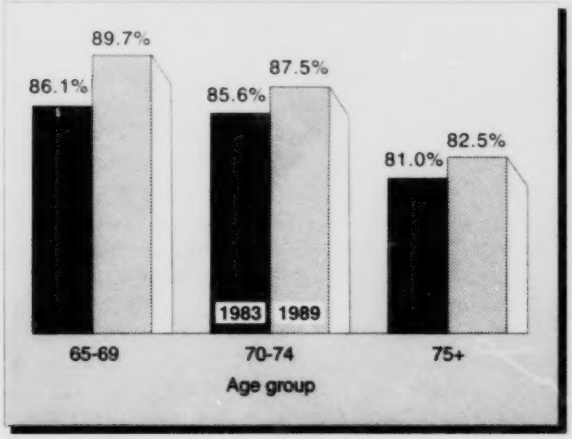
The results of this exercise are presented in Figure 2-5. The first bar shows the actual overall increase in ODB expenditure between 1981/82 and 1987/88. The next five bars show the change in ODB expenditure that would have taken place if $\propto$, Z, $\bar{q}$, *dc*, and *df* had each assumed their 1987/88 values, all others remaining at their 1981/82 level. The sum of these individual components is less than the actual increase because there are interactions that are not taken into account using this procedure. The final bar shows the impact on expenditure due to the increased servicing of patient/consumers. In deriving these estimates a number of assumptions have been made, so they should be regarded as approximations only.

Increases in ODB expenditure seem to be primarily due to the growth in the eligible population, Z, the jump in the number of claims per beneficiary, $\bar{q}$, and increasing drug costs per claim, *dc*. Each of these was responsible for about a 20-to-24 per cent rise in ODB expenditure. In the case of *dc*, this is almost entirely due to a rise in single-source drugs, since prices for interchangeable drugs actually *fell* in real terms over the period 1981/82 to 1987/88. Of much lesser importance was the increase in $\propto$ and *df*, reflected, in terms of the latter, in the decline in dispensing fees as a proportion of ODB expenditure from 41.8 to 36.8 per cent during this period (Table 2-5).

The final bar in Figure 2-5 is the impact of increased servicing of the population, which accounted for close to 30 per cent of the increase in ODB expenditure. Although the

Figure 2-3

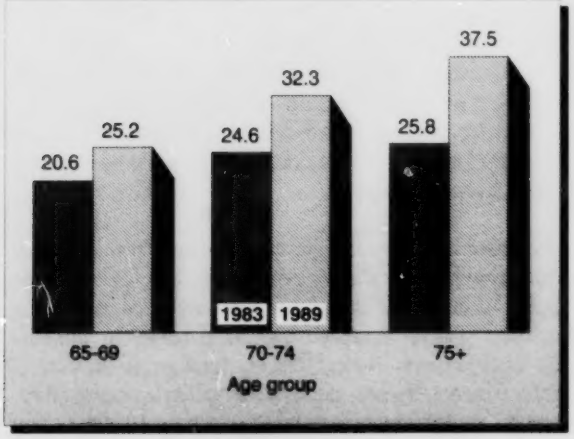
Proportion of the eligible population that are drug plan beneficiaries (∝), by age group, Quebec, 1983 and 1989



SOURCE Quebec, Régie de l'Assurance-maladie du Québec [1984, Tableau 68, 200, and 1990, Tableau 68, 216].

Figure 2-4

Average number of prescriptions per beneficiary, by age group, persons aged 65 and over, Quebec, 1983 and 1989

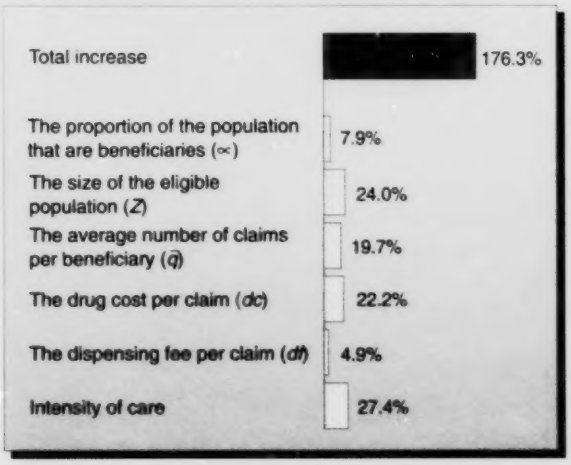


SOURCE Quebec, Régie de l'Assurance-maladie du Québec [1984, Tableau 68, 200, and 1990, Tableau 68, 216].

population did age between the early and late 1980s, this accounted for only a very small part of the change in the key parameters ∝ and $\bar{q}$. For example, the aging of the population would have seen $\bar{q}$ increase from 18.8 per cent in 1981/82 to 18.9 per cent in 1987/88, rather than the observed value of 22.5 per cent in the latter year. This is not altogether surprising given the relatively small change in the composition of the age structure of those aged 65 and over in this period.[15] Furthermore, it is consistent with a somewhat similar exercise undertaken for Saskatchewan [Saskatchewan Review Committee to the Minister of Health 1989, 19].

Figure 2-5

Components of the increase in 1987/88 in ODB expenditure over 1981/82 expenditure



While there are undoubtedly a variety of reasons for the increased servicing of the population, an important one is likely to be the growth in the supply of physicians in relation to the population and the increased activity per physician, partly induced by attempts to control fee schedule increases [Barer et al. 1988, Table 1, 22; Evans 1988, 5]. Another cause is the introduction of new drugs that replace surgical intervention, treat diseases for the first time, or offer substantial improvements over existing drug therapies.

These results suggest that important savings may be realized in the areas of eligibility, the factors behind the increased servicing of the patient/consumer, and the rise in single-source drug prices and the dispensing fee. However, attention also needs to be paid to levels, unless one is prepared to make the assumption that the levels in 1979/80 were, in some sense, optimal. What these numbers suggest is that increasing ODB expenditure cannot necessarily be ascribed to exogenous factors such as the aging of the population. Instead, it seems that an important cause of increased expenditure is within the health-care system itself. Controlling or monitoring this is likely to be easier than slowing down the aging of the population.

Table 2-5

Expenditure under the Ontario Drug Benefit, 1979/80 to 1987/88

	Total[1]	Dispensing fees	
	(Millions of current dollars)		(Per cent)
1979/80	110.3	49.8	45.1
1980/81	136.6	58.3	42.7
1981/82	171.0	71.5	41.8
1982/83	221.3	86.9	39.3
1983/84	263.5	102.5	38.9
1984/85	302.2	119.3	39.5
1985/86	349.7	129.9	37.1
1986/87	409.6	150.6	36.8
1987/88[2]	491.3	180.9	36.8

1 ODB claims with dispensing fees, which accounted for approximately 90 per cent of all ODB expenditure in 1986/87. The remaining 10 per cent consists of over-the-counter drugs, flu vaccine, and oxygen.
2 Estimate.
Source Ontario Ministry of Health [1988*b*, Appendix 3].

The Solutions

Expenditure under the Ontario Drug Benefit is the product of demand- and supply-side factors. On the demand side these include:

- the underlying health of the eligible population;
- the size and age structure of the eligible population;
- the proportion of the eligible ODB population that are program recipients or beneficiaries;
- the fact that ODB recipients receive drugs free of charge; and
- the fact that a prescription is the expected outcome of a consultation, whether on the part of the physician or the patient.

Supply-side factors include increases in:

- the number of physicians;
- the supply of drugs;
- the price of drugs; and
- the fee the pharmacy charges to the ODB for dispensing a prescription.

Thus expenditure under the ODB can increase for a wide variety of reasons.

Numerous solutions have been suggested for reducing provincial government drug expenditure, on both the supply and demand sides of the equation. These can be divided into three broad groups. The first essentially returns the situation, in part at least, to the status quo *ex ante*, by shifting part of the cost back to the private sector – the patient/consumer. These methods include:

- reducing the eligible population under the ODB;
- restricting drug benefits only to life-threatening situations;
- introducing patient/consumer copayment on either the dispensing fee or the total price of the prescription; and
- treating all drug benefits paid for under the ODB as taxable benefits.

Such measures do not necessarily reduce society's overall (public plus private) expenditure on drugs. Indeed, that may go up if the government has been particularly effective in restraining some element of cost which the private sector is not able to replicate as well. Furthermore, to the extent that public provision makes it easier for governments to incorporate the impact of drugs on the overall health-care budget, reducing public funding may increase overall health-care costs.

In the second set of solutions the government attempts to reduce the cost of delivering a given set of benefits to a defined eligible population. This can be achieved by:

- promoting – by mandating – the dispensing of the lower-priced generic brands;
- paying only for drugs where the evidence – using cost-effectiveness or cost-benefit analysis – suggests that the benefits substantially outweigh the costs;
- allowing carefully screened firms to import high-priced, high-volume, single-source drugs from the United States, the United Kingdom, or France;
- educating physicians to be more sensitive to alternative, less costly drug therapies;
- changing the method by which pharmacists are compensated for their dispensing and professional services to a more market-based system or to a completely different system, such as capitation; and

- pricing drugs for reimbursement under the ODB on the basis of a standing-offer-contract system, rather than the current best available price.

For these solutions to work, the government has to get not only the right set of incentives, but also accept that its actions may reduce the return to drug manufacturers, physicians, and/or pharmacists.

The third set of measures involves improving prescribing and therapy. It includes:

- drug utilization reviews designed to ensure better pharmacotherapeutic care and more cost-effective practice;

- monitoring and eliminating patient/consumer abuse of the ODB; and

- shifting the role of the pharmacist more towards patient-oriented services to ensure cost-effective use of medications.

The first two sets of solutions may be regarded – loosely speaking – as shifting the cost from government to patient/consumers and health-care providers. As such they are likely to encounter considerable opposition. The third set, if correctly implemented, has the possibility of not reducing any group's income, while raising the quality of care. However, it has the disadvantage that professional bodies may not like or accept the implied criticism of regulatory procedures designed to ensure appropriate drug therapy.

Several of these solutions have already been introduced by various provinces. For example, all provinces except Quebec and Ontario now have patient/consumer copayments; Saskatchewan uses standing offer contracts to price drugs; and drug utilization reviews are conducted in British Columbia and Saskatchewan. In the discussion of options and alternatives in Chapters 4 to 7, these experiences will be drawn upon in considering appropriate solutions.

The Approach

In discussing and evaluating the solutions to the problem of rising ODB expenditure, reference will be made to six broad principles or concepts: access; economic efficiency; program administration; value for money; the appropriate role for patient/consumers; and the right balance between the various roles of the Ontario Ministry of Health.

Access

Of the six principles, access is probably the one that commands the most acceptance across Canadian society. Access is part of a wider concept of equity. Public policies are frequently justified on grounds of equity. If a policy is felt to be inequitable, unjust, unfair, or not in accordance with generally accepted notions of what is "right" and "proper," it is unlikely to command either legitimacy or funding for long.

Many feel that a mark of a humane society is that those who have health problems do not suffer adverse consequences because of lack of access to drugs. Those least able to survive financially should be cared for by the rest of society. Access or societal fairness implies that Ontario residents who do not command sufficient income to purchase drugs, where in the opinion of a qualified medical practitioner these are warranted, should have them provided from the public purse.

Securing access to health care for all residents of Ontario is a key objective of government health policy. In a recent discussion paper on the future of health care in Ontario, the Minister of Health said:

> To better meet our needs, we have to make changes in the way health care services are delivered and funded. A key principle of Canadian health care – reasonable access of quality care for everyone – must and will remain intact. Health care must and will be provided to Ontario residents regardless of their ability to pay [Ontario Ministry of Health 1989*b*, 1].

Similarly, one of the five goals of the Ontario Premier's Council on Health Strategy [1989] is to "provide accessible, affordable, appropriate health services for all."

Economic Efficiency

Resources are scarce, there are numerous demands on their use, and these demands cannot all be met simultaneously. Thus it is important to ensure that resources are allocated in an optimum fashion – that is to say in such a way that they cannot be reorganized to provide, say, an extra hospital while leaving total output unchanged.

Optimum resource allocation, to simplify considerably, requires that, at the margin, the cost of an extra unit of production – whether a good or service – is equal to the price of the unit. In other words, price does not exceed cost. Implicit in this is that the resources for production of the good or service are being used in the least-cost manner. In the case of the health-care system overall, this means that all the parts of the system, from hospitals to pharmacists, are organized in such a way that the desired level of health care is delivered at least cost. This requires that careful attention be paid to the connections between the various parts

of the health-care system to ensure that each is aware and takes into account the costs and benefits it is imposing on other parts of the system.

For resources to be allocated efficiently – both at a point in time and over time – they should be able to flow from one use to another, and mechanisms should be in place to ensure that within any market, prices and costs are equated at the margin. In other words, if one form of drug distribution or pharmacy size provides a given level of professional services more efficiently, it should be allowed to expand and others contract, either in relative or absolute terms. Clearly, in some parts of the health-care system such reallocation can be achieved more quickly than in others.

Program Administration

Government intervention should be based on a well-documented case for the need for it. Furthermore, while this is a necessary condition, it is not a sufficient condition. There are costs to government intervention, so what is being compared is two imperfect models, the status quo and government intervention [Wolf 1988]. A sufficient condition is that the government intervention not be accompanied by costs that offset the benefits. In other words, the cure must not be worse than the disease.

Once government has intervened, the policy objectives should be well specified and understood. This makes both policy evaluation and administration easier. Implementation should be conducted with the maximum of transparency, so that those affected feel that the rules are being applied equitably, and deviations from program or policy objectives should be minimized. The administration of the policy should be as simple and straightforward as possible. For example, making many exceptions or attempting to craft the administration to meet many different and special situations may make the administration not only cumbersome, less efficient, and more costly, but it may also make meeting the primary policy goals and objectives more difficult.

Value for Money: Monitoring Outcomes

Government purchase of drugs and the professional and dispensing services of pharmacists under the ODB should improve the health and quality of life of the eligible population. In other words, for every dollar of public (or private) expenditure on drugs and pharmacists' services, there should be at least a dollar's worth of benefits.[16] Estimating whether such relationships hold is not easy or straightforward. The Ontario Ministry of Health has recently become concerned about this issue. The direction the ministry is going in this respect is as follows:

- improve and transmit knowledge on treatment outcomes and validation to make better use of resources and ensure quality of care; and

- encourage all health professionals to take an active role in implementing outcome review using technological assessment methodology to evaluate new equipment, drugs, and medical procedures [Ontario Ministry of Health 1989*b*, 26].

Solutions that involve a better appreciation or specification of the services purchased and monitoring of outcomes should, other things being equal, be encouraged.

The Role of the Patient/Consumer

In considering the practicality of various solutions to the issue of rising ODB expenditure, an important issue is the role of the patient/consumer.[17] In a well-functioning market, the consumer is able to judge the relative merits of different brands of toothpaste, makes of automobiles, or the quality of service provided by a discount as opposed to full-service broker. Sellers communicate the virtues of their products and services through a variety of media and methods.

In the case of health care, the conventional wisdom is that the consumer does not possess the required knowledge and expertise to operate in a similar manner. Physicians intervene and make decisions for patient/consumers with respect to diagnosis, treatment, and sometimes brand of drug. Patient/consumers then take the prescription to the pharmacist. This does not preclude, of course, patient/consumers discussing drug therapy and perhaps price with their physician and pharmacist.

Some solutions to health-care cost problems such as a small deterrent fee per visit to a physician implicitly assume that patient/consumers can judge when such a visit is warranted, and that they have the required expertise to distinguish between "essential" and "unessential" visits. Nevertheless, while it is generally agreed that such deterrent fees do not have a sound rationale, there is much less agreement on whether patient/consumers have the ability to judge the different pharmaceutical services provided and select the most appropriate one. If, for example, patient/consumers do not use pharmacists to gain information about drug therapy, then only the dispensing function of the pharmacist may be necessary. In other instances both the product and professional services will be required. Here at least the

beneficiary under the ODB might act as a consumer rather than a patient. Hence, ensuring the appropriate patient/consumer role is an important criterion in judging various solutions.

The Role of the Ministry of Health

The Ontario retail drug market is the result of successive government intervention since the late 1960s and early 1970s. By setting certain market-wide rules with respect to, for example, interchangeability, the use of the formulary, and the provision of information on drug costs and dispensing fees to patient/consumers, the government has intervened directly to influence drug cost and dispensing fee. The decision in the mid-1970s to establish the ODB has led to direct government influence on the 40 to 45 per cent of the market accounted for in the mid-1980s by the ODB. This direct intervention has also had an indirect impact on the rest of the retail drug market in Ontario.

Discussion of the performance of the Ontario retail drug market must consider the impact of any changes on the public and private sectors.[18] If, for example, the government successfully reduces its expenditure but there is a more-than-offsetting increase in private expenditure, then it is not clear that this is a benefit to society as a whole. Indeed, society may be worse off if total expenditure on health-care increases and the only change is a shift in the balance between the public and private sectors.

3 Government Intervention in the Ontario Drug Market: Origins, Evolution, and Rationale

Over the past 20 to 25 years provincial governments in Canada have intervened extensively in the retail drug industry. Indeed, one could say that the present structure and performance of the industry have been largely shaped by such intervention. That intervention has occurred at two interrelated levels: first, in setting the rules that govern the interplay of market forces across both the public and private sectors; and, second, in creating publicly funded drug programs. Although there are many differences in the ways the provinces have intervened, their policy objectives and instruments are strikingly similar.

In describing the role of government in the Ontario retail drug market, we will discuss several reports that ultimately led to the passage in 1986 of two major pieces of legislation: the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act. The following four chapters evaluate the impact of this legislation in solving a number of long-standing problems with government intervention.

Prescriptions at Reasonable Cost and Product Selection, 1969-74

In the 1960s, there was concern that drug prices were too high and that existing lower-priced brands were unable to penetrate the market because of doubts about their quality and safety. This led to a number of federal and provincial policy initiatives.

Federal Initiatives

The federal government adopted a twofold strategy. First, in 1969 it amended the Patent Act to allow compulsory licences to be issued to manufacture and/or import drugs still subject to patent protection. This greatly facilitated the introduction and distribution of generally lower-priced brands, particularly for high-volume drugs. Second, in 1971, to address concerns about the quality of these brands – which were often marketed by smaller, Canadian-owned firms – the federal government introduced the Drug Quality Assurance Program to disseminate information to health-care professionals.[1] However, the function of this program soon shifted to providing the information directly to provincial governments, to assist them "in the selection of drugs for their drug reimbursement or purchasing programs" [Canada Department of Health and Welfare 1977, 8]. This is the function it performs today.

Pharmacy Initiatives

In the 1960s pharmacists became dissatisfied with the mark-up-over-the-cost method of compensating them for their dispensing and professional services [Commission on Pharmaceutical Services 1971, 252]. They increasingly favoured fixed dispensing fees that are unrelated to drug costs rather than a mark-up, the system that is still used today for over-the-counter products. The change came about in the 1960s as a result of several factors. According to Carruthers et al. [1987, 136], it "was developed in response to the expressed wishes of the pharmacy profession who preferred to be compensated on the basis of a professional fee, in much the same way that physicians are paid for their services." However, it was also recommended by those interested in lower drug prices, since a fee would remove the incentive to dispense higher-priced brands [e.g., Canada Special Committee of the House of Commons on Drug Costs and Prices 1967, 35].

Provincial Initiatives

Complementary measures were taken by a number of provincial governments [Gorecki 1981]. Ontario, one of the first, introduced PARCOST – prescriptions at reasonable cost – in 1970.[2] An important part of the PARCOST program was the *Comparative Drug Index* (CDI), a semi-annual publication that listed the prices of different brands of particular drugs by dosage form and strength. Only drugs of a quality deemed acceptable by the Drug Quality and Therapeutics Committee – an independent body composed of health professionals – were listed. The CDI was distributed to physicians and pharmacists to influence them to prescribe and dispense lower-priced brands. However, being included in the CDI did not certify two brands of the same drug as interchangeable pharmaceutical products in the sense that they have the same therapeutic effects and are chemically the same, nor did the policy exempt either physicians or

pharmacists from legal liability if a different brand from that prescribed was dispensed.

It is important to note that PARCOST was accepted by the Ontario Pharmacists' Association (OPA), the organization primarily responsible for representing the economic interests of pharmacies in Ontario. Specifically, an agreement was signed by participating pharmacists and the OPA whereby the pharmacists agreed to dispense, whenever possible, the drugs listed in the CDI. In addition, they agreed to charge no more than the cost of the drug listed in the CDI plus a *maximum* dispensing fee negotiated with the Ministry of Health. In order to encourage pharmacists to enroll in PARCOST, prices were deliberately set to reflect the purchase of relatively small packages which can be readily stocked by even the smallest pharmaceutical outlet. In many cases the prices listed in the CDI also included a 10-percent wholesale margin "since it is assumed that some of the smaller pharmacies would have to purchase the product ex wholesale warehouse" [Bailey et al. 1978, 3]. Participating pharmacies were identified by a decal, and the government funded advertising to inform the public, who was primarily paying cash at that time. By January 1973, 59 per cent of pharmacists in Ontario had signed a PARCOST agreement, although many others followed PARCOST principles but had not signed a contract [Ferguson et al. 1973, 12].

In 1971 the Porter committee was charged by the Minister of Health with examining the rules and procedures permitting pharmacists to select a different brand from that prescribed, since the brand prescribed was often the higher-priced patented product, particularly for newer drugs. It recommended that pharmacists be empowered to select and dispense a comparable pharmaceutical product[3] "provided that the cost of such product to the consumer is equal to or lower than the lowest priced comparable pharmaceutical product listed in the PARCOST Comparative Drug Index" [Porter et al. 1971, 1]. This recommendation was made only after the committee was satisfied that the procedures and knowledge of the Drug Quality and Therapeutics Committee were sufficient to ensure therapeutic equivalence or interchangeability. It also commented that "government should accept whatever legal liability that might emanate from the CDI," although this was not a formal recommendation [Porter et al. 1971, 9].

In 1972 the provincial Pharmacy Act was amended to allow permissive product selection and exempt pharmacists and physicians from legal liability.[4] In other words, selecting a different brand from that prescribed – product selection – was at the discretion of the pharmacist. Pharmacists had to select from those brands listed as interchangeable in the CDI and choose a brand lower in cost than the drug prescribed. In fact, they had to supply a product at a price not in excess of the listed price for the lowest-priced interchangeable pharmaceutical product in their inventory and the maximum dispensing fee as set out in the CDI.

PARCOST was reviewed in 1972/73 by a task force established by the Ontario Council of Health at the request of the Ministry of Health to see whether it was "achieving its objective to provide prescription drugs at reasonable cost for the people of Ontario" [Ferguson et al. 1973, 5]. The task force concluded that the program generated substantial savings compared with its costs, and that there appeared to be considerable confidence in the CDI.

The task force was concerned, nevertheless, about efforts by some of the major drug firms to cast doubt "on the efficacy of the less expensive products listed in the CDI as interchangeable with the more expensive ones" [Ferguson et al. 1973, 9]. It was satisfied, however, that "the best available modern methods for evaluating drugs" were used to admit drugs to the CDI and that "admirable and objective judgement" was used in making these decisions [1973, 13]. It made a number of recommendations designed to strengthen confidence in interchangeability and the CDI, such as the establishment of an information program aimed at health professionals to emphasize the quality of PARCOST. Although no formal program was implemented, some measures – such as the provision of more information in the CDI – were taken in the spirit of these recommendations.

The task force also recommended that for a generic prescription, for example, diazepam rather than one of the many different brands such as Valium, Vivol, Novodipam, or E-Pam, only a product listed in the CDI be used and that it be the lowest-priced interchangeable product in the pharmacist's inventory.[5] This recommendation addressed the apparent loophole in the 1972 amendments to the Pharmacy Act that no reference was made to generic prescriptions, since most prescriptions were written by brand name.

The pharmacist was therefore "permitted to select any preparation in his inventory which corresponds to the description. It could be the most expensive one, although that presumably would not be the intention of the prescriber. It could also be the cheapest but of a quality not approved for inclusion [in the CDI]" [Ferguson et al. 1973, 5]. Changes were made to the Health Disciplines Act (into which the Pharmacy Act was incorporated) in 1974 and proclaimed in July 1975, stipulating that a generic prescription was to be priced at no more than the listed cost of the lowest-priced interchangeable pharmaceutical product in the pharmacists' inventory plus the PARCOST negotiated dispensing fee.[6]

Commentary

There are sound rationales for this intervention by the Ontario government in the retail drug industry between 1969 and 1974. PARCOST addressed the problem of inadequate provision of information about drug quality, safety, and interchangeability.[7] Information of this sort may be undersupplied by the market because of its unique characteristics. Once the information is produced, it may be difficult for those who do provide it to recover their costs. Those firms with the greatest incentive to supply such information – generic firms – may have credibility problems with health professionals. Since it is in the interest of society that such information be provided, then government has a rationale to intervene. The establishment of the Drug Quality and Therapeutics Committee – an independent committee of medical and pharmaceutical experts established to make judgments and recommendations concerning quality and interchangeability – was intended to provide the necessary confidence of physicians, pharmacists, and patient/consumers in the CDI.

In introducing the product selection rules, the government was intervening on behalf of patient/consumers to ensure that the drug market functioned like any other market. The retail market for both pharmacists' services and prescription drugs was not (and is not) in general competitive, in that professional statutes and regulations severely restricted the information pharmacists could disclose about the dispensing/professional services they offered or the prices of drugs. It is also likely that patient/consumers had difficulty judging the information on different brands of individual drugs.

The Ontario Drug Benefit Program: 1974-76

The Ontario Drug Benefit (ODB) program was introduced in 1974 to provide free drugs to "needy senior citizens, and to persons receiving social assistance." The following year it was extended to include "all Ontarians 65 years of age and over, who received Old Age Security, or who resided in Ontario for the past 12 months and were Canadian citizens or landed immigrants" [Ontario Ministry of Health 1988*c*, 6-7]. In 1976 persons eligible for drug assistance from municipalities through the general welfare assistance legislation came under the ODB. Coverage has remained essentially unchanged since 1976, apart from a few minor additions in 1989.[8]

Under the ODB, eligible patient/consumers were provided with drugs free of charge at the point of dispensing. They received a card indicating that they were beneficiaries under ODB, which they presented to the pharmacist.[9] The provincial government reimbursed pharmacists for their services and the drug cost upon receipt of a claim. Funding was open-ended in that given the eligible population, the list of drug benefits and associated prices, and a negotiated dispensing fee, the provincial government paid all valid claims. This remains essentially unchanged today.

The role of the ODB has grown considerably. In 1975, its first full year of operation, it accounted for approximately 17 per cent of prescriptions dispensed by retail pharmacies [Spitzer et al. 1988, 4]; in 1978 it accounted for 25 per cent of the dollar volume of Ontario drug prescriptions [Bailey et al. 1978, 8]. At the present time the ODB accounts for approximately 40 to 45 per cent of prescriptions dispensed by retail pharmacies [Ontario Ministry of Health 1988*b*, 1]. These figures are consistent with those of the Department of Health and Welfare (see Table 1-2).

All drug benefits under the ODB and the reimbursement price were listed in the 1974 *Drug Benefit Formulary* (DBF). Unlike the CDI, in the DBF only one price was listed for a group of interchangeable pharmaceutical products. For example, for diazepam 10-mg tablets the following appeared:

	Brand name	Firm name	Price
Drug identification number			
260339	E-Pam	ICN	0.0404
013773	Vivol	HOR	
272450	Novodipam	NOP	
013293	Valium	HLR	

Source: Ontario Ministry of Health [1974, 35].

The price listed was that of the lowest-cost brand. In August 1975, after only two issues, the DBF was merged with the *PARCOST Comparative Drug Index*. The combined publication became known as the formulary. In the merged publication all the prices were listed, but the lowest price was printed in bold typeface. Thus the listing for diazepam 10-mg tablets was as shown in the box on page 24. The *PARCOST Comparative Drug Index* and the *Drug Benefit Formulary* have remained one publication to the present. With the passage of Bills 54 and 55 in 1986, the prefix PARCOST was dropped.

There were some similarities and differences between the ODB and non-ODB markets with respect to dispensing fees,

Drug identification number	Brand name	Firm name	Price
280429	E-Pam	ICN	0.0237
303461	Diazepam	SAP	0.0240
272442	Novodipam	NOP	0.0255
288713	D-Tran	MOM	0.0278
311588	Diazepam	MPT	0.0278
284076	Serenack	CPN	0.0352
037265	Paxel	ELL	0.0469
013765	Vivol	HOR	0.0550
013285	Valium	HLR	0.0702

Source: Ontario Ministry of Health [1975, 33].

drug costs, and the quantity dispensed. There were certain general rules that applied to all of the market, and some arrangements that covered only the ODB sector. However, as we shall see, some of the arrangements that were initially confined to the ODB sector became common practice in the entire Ontario market.

The ODB and the pharmacists, through the Ministry of Health and the OPA respectively, negotiated a dispensing fee as part of an overall Participation Agreement that set out the terms and conditions of a pharmacy's involvement in the ODB. Apart from the first few years, the ODB and the Parcost fee were identical [Gordon 1984, Appendix B]. The government would reimburse the lower of the pharmacy's usual and customary dispensing fee charged to the general public and the Parcost fee. This was the "marketplace" concept introduced in the 1976 Participation Agreement, designed to prevent pharmacists from charging the government a higher rate than that charged in the non-ODB market, or, alternatively, to allow the ODB to benefit from any price competition in the non-ODB market [1984, 29-30]. In its annual reports in the late 1970s, the Ministry of Health highlighted the "marketplace" concept as an effective cost containment method.

Under the ODB, pharmacists were reimbursed for a particular interchangeable product for an amount no more than the lowest-priced brand listed, irrespective of which brand was actually dispensed and whether or not they had the lowest-priced brand in their inventory. For example, according to the first combined CDI/DBF, pharmacists were reimbursed $0.0237 for diazepam 10-mg tablets, whether E-Pam or Valium was dispensed.[10] This was referred to as the maximum allowable cost.

In the non-ODB market, product selection was permissive. Pharmacists who decided not to product select and did not belong to Parcost could charge whatever they liked for the drug and the dispensing fee – their usual and customary fee. However, it appears that they usually used the formulary as a pricing guide for individual brands of a drug [Gordon 1984, 37]. Thus if their usual and customary fee exceeded the Parcost fee, pharmacists had no incentive to belong to Parcost or to product select.

Under the ODB only one dispensing fee was charged per month's course of treatment, irrespective of whether the prescription was for a 100-day or a 10-day course of treatment. Strictly speaking, this only applied to maintenance drugs, or so-called circle one drugs. Approximately 70 per cent of ODB claims fell into this category in the early 1980s [Gordon 1984, 30]. For other drugs, if more than one claim was made in a month then more than one fee was allowed.

The one-month-supply-per-fee rule reflected the fact that at first the ODB only covered needy senior citizens and persons receiving social assistance (for which they qualified on a monthly basis). However, when the ODB was extended a year later to cover the drug costs of all those aged 65 and over, the rationale for only allowing one month's supply per fee largely disappeared. Older people are often on maintenance drugs, for which much longer courses of treatment than a month can safely be dispensed at one time. Nevertheless, when the ODB was extended to all older people, the one-month-supply-per-fee rule remained as part of the Participation Agreement.[11] However, it should be noted that until 1977 the ODB dispensing fee remained somewhat below the Parcost fee in recognition of this; later the two were identical [Gordon 1984, Appendix B]. In the non-ODB market there was no such rule, but apparently it became common practice to dispense monthly courses of treatment – even if the prescription was for longer – and collect a dispensing fee for each month's supply.

The Rationale for the ODB

Two aspects of the rationale for government intervention through the ODB will be addressed here: first, the objectives of, and justification for, the ODB; and, second, the rules for reimbursing pharmacists for ODB dispensing fees and drug costs, and how they interacted with the non-ODB market.

The objective of the ODB, according to the Ministry of Health, is "to provide as a drug benefit to specified groups of persons, including senior citizens and welfare recipients, designated prescription drugs with the intent of alleviating the financial burden of drug therapy."[12] A similar rationale was adopted in 1988 when the Minister of Health agreed to implement an interim recommendation of the Pharma-

ceutical Inquiry of Ontario that medically indicated drugs and drug-related therapies be made available at no charge to sufferers of cystic fibrosis and thalassaemia.[13] The Minister stated: "I want to make sure that these two special groups, who face catastrophic drug costs, have equity in access to the drugs they need" [Ontario Ministry of Health 1988*d*, 1].

Although there is a clear rationale for the ODB, the way in which the program is structured is not entirely congruent with its objectives. There is a presumption that the program is alleviating the financial burdens of beneficiaries. While this is clearly the case for the pauper, it is not the case for the millionaire over 65 years of age. If the rationale for the ODB is to provide relief from catastrophic costs, it is not clear why all costs have to be borne by the government. In other words, the ODB is excessively generous given its rationale and objectives – more public funds are being dispersed than is necessary to meet the program's stated objectives.

There are two possible reasons for this excessive generosity. One is that many people disapprove of the idea of means-testing for benefits. Thus the Pharmaceutical Inquiry of Ontario [1988*b*, 13] said of extending drug benefits to cystic fibrosis and thalassaemia patients that the "affected person or family should not have to prove financial need in order to receive a life-preserving benefit." The second is the argument that if a benefit is not made available to all within a particular group irrespective of income – in the case of the ODB those aged 65 and over, the largest group of beneficiaries (Table 2-2) – the program will lose support and may disappear.

The second aspect of government intervention between 1974 and 1976 that we consider here is the establishment of rules and procedures to determine the ODB dispensing fee and ingredient cost, which were built upon the foundations established by Parcost. The dispensing fee was determined by the marketplace concept, which, according to the Ministry of Health, "makes allowance for variations in operating costs of different pharmacies and at the same time ensures that government will pay no more than the public." The ministry considered the policy a success, because "the actual average fee paid for drug benefit prescriptions was $2.24" [Ontario Ministry of Health 1976, 30]. The maximum negotiated fee during the period from January to July 1976 was $2.60. In other words, a cap was set on the fee, but local conditions resulted in lower fees in some markets.

The marketplace principle seems a sensible policy. Initially, at least, the ODB only accounted for a small percentage of the Ontario retail drug market – less than 20 per cent in 1975 (Table 1-2 on page 5). It could thus be argued that the ODB could safely rely on the remainder of the market to determine the appropriate dispensing fee. Some such mechanism was clearly necessary, since ODB beneficiaries did not make any financial contribution towards the dispensing fee. They thus had no incentive to patronize pharmacies with lower fees; convenience and quality of service were probably the major criteria for choosing a particular pharmacy.

Nevertheless, the marketplace concept did have some drawbacks. It was based on the premise that the retail drug market was competitive,[14] that there was a well-functioning market in which buyers and sellers were well informed, where there were appropriate incentives to select and offer the best combination of price and quality of service. However, it is doubtful that such a characterization applied to the retail pharmacy market. There were substantial regulatory barriers preventing pharmacies from informing patient/consumers of their dispensing fees and the range of professional services available. At the same time, the sensitivity to prices of an increasingly large section of the population was decreasing as more and more people were covered by insurance plans of various kinds. These plans apparently adopted the fees set in the marketplace for reimbursement purposes.

The ODB pricing rules ensured that for interchangeable drugs the government reimbursed pharmacists only up to the cost of the lowest-priced brand listed for a group of interchangeable products. Since the government had introduced legislation and procedures to guarantee interchangeability, this again seems a sensible policy, given the difficulty of introducing a competitive market in the sale of prescription drugs. What is not clear is why such rules were not applied to the private sector. In the non-ODB market, consumers paid at least the ODB price and probably more, depending upon the volume of lower-priced brands prescribed and dispensed.

What was the impact of government intervention in the retail drug market over this period? In the mid-1970s, the Ministry of Health conducted a survey that covered both the public and private sectors of the retail drug market. In a study using this survey, Gorecki and Klymchuk [1980] concluded that the impact of government intervention was to bring about uniform prices for a given brand, dosage form, and strength of a particular drug across two store types (chain and independent), four geographic regions (Metro-Toronto, Southwestern and Niagara, Georgian Bay and Northern, and Eastern), and six prescription classes (including ODB, no-substitution, third-party, and cash-paying). Thus formulary prices had become the basis for retail prices in Ontario.

The survey also found that for interchangeable drugs many of the brands were priced significantly higher than the lowest-priced brand. This raises the possibility that non-ODB customers paid a higher price than the government for interchangeable drugs because of the absence of product selection. Finally, the study posited that the evidence was consistent with the view that the pharmacists' usual and customary dispensing fee was priced in such a way that it led to upward pressure on the ODB-negotiated maximum fee. In other words, the usual and customary fee was set just above the maximum negotiated fee. Thus, while government intervention was well intentioned, it is not clear that the lowest attainable fee was achieved or why ODB rules for drug pricing were not extended to the entire Ontario drug market.

Solving Problems: Drug Prices, Dispensing Fees, Dispense Quantity as Written, 1976-86

The period from the inception of PARCOST in 1970 to the establishment and extension of the ODB in 1974-76 saw the creation of a framework of rules and regulations that set the basic parameters of the Ontario retail drug market with respect to prices, dispensing fees, and the length of treatment dispensed, and the split between the public (i.e., ODB) and private (i.e., third-party programs and cash-paying customers) sectors. In the period 1976-86 some of the problems that arose out of this framework were investigated and attempts were made to correct them.

Two major reports were released in this period – the Bailey committee report in 1978 and the Gordon commission report in 1984. While some of the recommendations of the Bailey committee were implemented in the late 1970s, they had little impact beyond a year or two. Nevertheless, the combined weight of these two reports, the failure to successfully implement some of the Bailey recommendations, and a growing chorus of disapproval from such disparate bodies as the Ontario Advisory Council on Senior Citizens and the provincial auditor eventually led to the introduction of two major pieces of legislation, Bill 54, which was passed as the Ontario Drug Benefit Act in 1986, and Bill 55, which became the Prescription Drug Cost Regulation Act, also in 1986.

Purchasing Advantage and Price-Spread

A major concern in the late 1970s was that the drug prices listed in the formulary, particularly for those of high-volume interchangeable drugs, were too high for two reasons. First, the prices were based on smaller package-sizes, which were not always appropriate. Second, the prices quoted in the formulary for a given package size were above the actual transaction prices.

Although the prices that the Ministry of Health requested of manufacturers for inclusion in the formulary were for smaller package-sizes such as 50s and 100s and not larger package-sizes such as 500s and 1,000s, it was recognized that some pharmacists would purchase the larger package-sizes with consequent savings. This margin, the so-called purchasing advantage, was always considered legitimate; indeed it was mentioned specifically in the formulary. The first time was in the July 1978 formulary, which contained the following statement:

> Where more than one package size is available, the one selected for listing indicates the most economic and efficient size for an average community pharmacy to purchase. It is recognised that lower prices will be realized through efficient operational practices and bulk purchasing, and improvements in this regard will be stimulated and encouraged [Ontario Ministry of Health 1978, v].

Similar statements appeared in later formularies before the passage of Bills 54 and 55. The concern was that for some high-volume drugs the average community pharmacy was purchasing in packages of 1,000, so the higher unit price of the packages of 50 or 100 should not have been used as the basis for reimbursement.

The other concern was that some manufacturers were deliberately quoting unrealistically high list prices for inclusion in the formulary, irrespective of the package size, and then using the difference between the list price and the actual or transaction price to pharmacists as a marketing device. The list price could be charged in the marketplace, and the difference could be captured by the pharmacist. In other words, manufacturers did not compete by getting the lowest price in the formulary, but by maximizing the difference between the price quoted in the formulary and the actual or transaction price, as a way of getting pharmacists to stock their particular brand. This is known as "working the spread." The remark by Porter et al. [1971, 15] that "it would appear to be incredibly difficult to ferret out misleading list prices or special deals" was therefore a prescient one.

The Bailey Committee

These concerns over prices led the Minister of Health to strike the Bailey committee in October 1977, which reported in April of the following year. It found that "although the Formulary prices are almost invariably based on relatively

small package sizes such as 100s, the vast majority of the high volume products are normally purchased in substantially larger packages" [Bailey et al. 1978, 12]. For example, the percentage of total unit sales in larger packages (typically 1,000s) among 13 high-volume drugs varied between 82 and 99 per cent, with an unweighted mean of 95 per cent [1978, Table A].

The committee also found evidence that the prices quoted for the package size listed in the formulary were indeed too high in relation to the actual or transaction prices. It found that:

> On some major items the smaller package sizes represent an insignificant portion of total sales. Therefore there is no need for the manufacturer to quote such package sizes competitively for the Formulary, since these small packs are seldom purchased. On the other hand, the aggressive competition among drug manufacturers in high volume fields forces the true cost to the pharmacist to relatively lower levels in the larger package sizes commonly purchased.

The committee continued:

> In verification of the above, certain manufacturers have acknowledged that the present system is "self-defeating" in that it actually forces manufacturers to raise prices quoted to the government and then price their products attractively to those pharmacists who "work the spread" (i.e. – capitalize on the difference between the quoted price versus the actual cost) [1978, 12].

Thus these two issues – the use of smaller package-size prices and the spread – were connected.

The committee recommended that for certain high-volume drugs the price in the formulary be based on large package-sizes, and that the actual acquisition or invoice cost be used. This was implemented in 1979 for 36 high-volume drugs, whose prices were now based on package sizes of 1,000 rather than 100. For example, the price of the lowest-priced brand of diazepam 10-mg tablets fell from $0.0300 in the July 1978 formulary to $0.0105 in the January 1979 edition; that of the 5-mg tablets fell from $0.0236 and $0.0062.[15] However, $0.22 was added to the ODB dispensing fee as compensation to the pharmacists [Gordon 1984, 30-31].

The Bailey committee went far beyond the issue of whether the prices in the formulary were "realistic." Indeed, it could be argued that its report, despite its brevity, was the most radical and perhaps insightful of the reports reviewed here. On the fact that the formulary listed the unit price of all brands, even though the ODB paid only the lowest price listed for interchangeable pharmaceutical products, the committee commented that since the formulary "has become accepted as a pricing guide throughout Ontario and even to some degree in other provinces . . . prices quoted in this government publication may create a hardship for a large segment of the population" [Bailey et al. 1978, 12]. The committee recommended that for interchangeable drugs only a single price be listed, as had been the case in the first two ODB formularies issued in 1974. This recommendation was implemented in the January 1979 formulary for one issue only. Subsequently the formulary reverted to listing all prices; apparently the College of Pharmacists convinced the Ministry of Health that all the prices had to be published to enable the college to enforce Section 155 of the Health Disciplines Act as it related to product selection of lower-priced brands.

The Bailey committee also made a series of additional proposals, some of which were implemented in Bills 54 and 55 (they are reprinted in full in Appendix A). It recommended that in the non-ODB market

> provision should be made to enable the cash paying public to make a rational choice of pharmacies when having prescriptions filled. Pharmacies should be allowed to declare their dispensing fee through both the advertising media and by means of discreet plaques or cards at the pharmacist entrance or in the dispensing area [Bailey et al. 1978, 15].

It also proposed that the public be informed of the prices paid by the ODB and that less costly interchangeable pharmaceutical products are frequently available. The committee also suggested that a token copayment under the ODB be introduced to discourage overutilization [1978, 16].

On the issue of multiple dispensing fees for long periods of treatment, the committee proposed that:

> The common practice of dispensing only 30 days medication to senior citizens should be modified in view of the fact that most of these individuals are on long term therapy and many find it inconvenient to visit the pharmacy monthly. Dispensing of more rational quantities at one time should result in substantial economies to the pharmacy. These savings could be passed on to the taxpayer, and at the same time the hardship of repeated visits to the pharmacy by the ODB recipients could be alleviated [1978, 16].

Finally, the Bailey committee recommended that "a reasonable extra margin should be allowed to the retail merchant who buys in quantity," and that it be fixed at 10 to 20 per cent [1978, 15].

The Gordon Commission

The major problem addressed by the Bailey committee – that of inflated formulary drug prices – did not go away. In

fact, it got worse in the early 1980s. Quoted in the auditor's 1983/84 report, the ministry estimated that for 18 high-volume interchangeable drugs, the difference in 1983 between the lowest price in the formulary and actual drug costs to pharmacists was $14.4 million, or about 5 to 6 per cent of total ODB expenditure on drugs and fees [Archer 1984, 83-85].

In the February 1984 formulary, prices were lowered for 30 high-volume interchangeable drugs in order to reduce or eliminate the difference between actual or transaction prices and formulary prices. Overall, the average drug cost per ODB claim for interchangeable drugs fell from $4.98 in the period between July 1983 and January 1984 to $4.09 in the period between February and June 1984 (Table 7-1). For example, the price of the lowest-priced brand of diazepam 5-mg tablets[16] fell from $0.0197 in the July 1983 formulary to $0.0030 in the February 1984 edition; the price of cimetidine 300-mg tablets fell from $0.1500 to $0.0967 over the same period [Ontario Ministry of Health 1983, 46 and Addendum; 1984, 46, 75] – this even after the July 1983 price of cimetidine had apparently been substantially reduced for that formulary [Archer 1984, 86-87]. The prices of 20 of the 30 high-volume interchangeable drugs were adjusted on the basis of package sizes of 1,000; the prices of the remaining 10 were adjusted on the basis of package sizes of 500. Of the former, 15 were among those whose spread the ODB had tried to eliminate only five years previously, on Bailey's recommendation [Gordon 1984, Appendix A]. As before, pharmacists were awarded an increase in their ODB dispensing fee – $0.35 compared with the previous $0.22 – to compensate for the loss of spread [Gordon 1984, 16-17, 82].

The Ontario government was also having considerable difficulty negotiating a dispensing fee with the OPA.[17] Part of the problem was whether the dispensing fee should increase if more realistic prices were entered in the formulary. Indeed, the need to resolve this issue, combined with the February 1984 drug price roll-back and the $0.35 fee increase, led to the creation of the Commission on the Pricing of Multiple-Source Drug Products in Ontario, the Gordon commission, in March 1984. The commission's terms of reference included, in addition to these issues, determining whether changes were required to Section 155 of the Health Disciplines Act, which governed product selection in Ontario. It reported in August of the same year.

Before turning to the specific recommendations of the Gordon commission, two general points should be noted. First, although there was substantial consensus among the four principal parties that were involved in the creation of the Gordon commission on the problems that plagued the Ontario retail drug market – such as the price-spread – there was substantially less consensus on the solutions. On the issue of the price-spread, for example, the Pharmaceutical Manufacturers Association of Canada favoured actual acquisition cost; the Canadian Drug Manufacturers Association wanted to see the ODB mandatory price selection extended into the non-ODB market and only one price listed for interchangeable drugs; the Ontario Pharmacists' Association favoured incremental, marginal change; and the Ministry of Health was prepared to consider dramatic changes [Gordon 1984, 51-58]. Second, the commission stated that it intended its recommendations "to introduce as little disruption into the retail prescription market as possible." After considering various alternative models, the report concludes that "the current structures have no more inherent faults than any other structures which could be contemplated" [1984, 78-79].

In many ways the Gordon commission's recommendations echoed those of the Bailey committee. It too found that price-spreading was widespread and recommended that the price in the formulary should be "no more than 20 per cent higher than the best volume price available from the manufacturer during the formulary period for the package size listed" [1984, 80]. This was to encourage pharmacists to purchase efficiently and manufacturers to price competitively. The report defined purchasing advantage as that "which arises from the pharmacist purchasing in bulk and thereby paying less than the index/formulary price for a drug product" [1984, 17]. It recommended that package sizes of 1,000 should remain the basis for determining the prices of high-volume drugs. Gordon recommended that the Ministry of Health should introduce penalties for manufacturers who submitted inaccurate price data for inclusion in the formulary; for example, ceasing to list their products as eligible benefits or restricting their price increases. While Bailey recommended that just the lowest prices for interchangeable drugs be published, Gordon recommended that all prices be published.

On the dispensing fee, the Gordon commission recommended that a single fee which would be applicable to both the ODB and PARCOST continue to be negotiated by the OPA and the Ministry of Health. As part of the process of determining the fee, cost information should be collected. Finally, the Gordon commission recommended that the dispensing fee should *not* be adjusted when formulary prices are lowered, as had happened in the past. In the commission's view, the dispensing fee and drug cost should be separate items and not linked.

The last major set of recommendations related to interchangeability. Under Section 155 of the Health Disciplines

Act, when pharmacists decided to product select in the non-ODB market, they *had* to charge the PARCOST dispensing fee, and no more than the lowest-priced interchangeable product in their inventory. A PARCOST pharmacy that did *not* product select could charge no more than the price of the brand prescribed as set out in the formulary, and the negotiated PARCOST dispensing fee. However, there was no legislation covering a situation where a pharmacy did not participate in PARCOST and decided *not* to product select. In practice it appears that pharmacists would set their usual and customary fee somewhat above the PARCOST fee, and the cost of the drug following the formulary. In this situation there was little incentive for pharmacists to participate in PARCOST or product select.

The evidence in the Gordon report shows that participation in PARCOST gradually dropped to only 15 per cent of Ontario pharmacies in 1984, and product selection ceased to be practised to a very great extent in the non-ODB market [Gordon 1984, 43-46]. The commission recommended that the legislation be amended to allow "pharmacies to charge a usual and customary fee when . . . product selecting" [1984, 83]. It also recommended that the selected brand be lower in cost than that prescribed, rather than being no more expensive than the lowest-priced brand in the pharmacist's inventory.[18]

Evidence in late 1985 suggested that for generically written prescriptions – diazepam rather than Valium or Apo-Diazepam – where pharmacists were supposed to charge up to the PARCOST dispensing fee whether or not they were PARCOST pharmacies, 80 per cent violated the legislation and charged a higher fee. The Registrar of the College of Pharmacists was unable to explain why that section of the act was not routinely enforced [Silversides 1985*a*, 1985*b*, and 1986].

The Gordon commission also made a series of secondary recommendations. These include a recommendation that patient/consumer copayment be introduced; that more information be supplied to the consumer concerning prices and dispensing fees; that waste of prescription drugs be reduced by more rational prescribing; and that physicians be educated as to the benefits of generic products.

It also recommended – as did the Bailey committee – that a dispense-as-written policy be implemented.[19] This recommendation commanded wide support. A joint report by the Ontario government and the Ontario Medical Association on controlling health-care costs in general expressed concern about the "dispensing of drugs on an unduly frequent basis" [Taylor et al. 1977, 25]. Subsequently, the provincial auditor in his 1979 report [Archer 1979, 81-84] and the Ontario Standing Committee on Public Accounts [1980, 37] in 1980 raised the issue of dispensing the whole quantity prescribed at once. At first the Ministry of Health doubted that the savings would be large. However, a study commissioned by the Ministry of Health and the OPA suggested a dispense-as-written policy would result in considerable savings [Woods Gordon 1981].

The dispense-as-written issue was then taken up by the Ontario Advisory Council on Senior Citizens. In June 1984, the council recommended to the provincial government that:

> Because of the difficulty of access for many senior citizens, particularly those in under-serviced areas, to pharmaceutical outlets at 30 day (or less) intervals; and in order to cut down prescription dispensing costs which are disproportionately higher for smaller quantity prescriptions; it is recommended concerning the rule of redispensation at intervals of thirty days for uncontrolled drugs that an extension from 30 to 90 days be considered, at the discretion of the prescribing physician [1985, 4].

Clearly the council had both the interests of the taxpayer and the senior citizen in mind when making this recommendation.[20]

The Role of Government

In the period 1976-86 the issue was not so much whether there was a rationale for government intervention, but rather how government should intervene to ensure its goals were met. As the discussion makes abundantly clear, the government was having some difficulty in meeting some of its goals, particularly establishing realistic prices in the formulary. Indeed, while Bills 54 and 55 were being debated in the legislature, the ODB was trying, once again, to eliminate the spread by reducing published formulary prices. This was the third time in seven years.

In the period 1976-86 the provincial government paid a lower dispensing fee and lower drug costs than the non-ODB sector. On the subject of the latter, the Gordon commission report said:

> In the non-Drug Benefit market . . . mandatory price substitution [which applies in the ODB portion of the market] does not apply nor, for that matter, does product substitution take place to any great extent. According to estimates given the Commission, of all prescriptions written about 20% are written generically and must be product selected, and another 40% are written for brand-specific multiple-source products, and are, therefore, eligible for product substitution. Substitution, however, takes place on only about 6 % of all prescriptions, or 15% of these prescriptions eligible for substitution. The savings being lost to the consumer by this low

> level of substitution are considerable. Using mandatory price substitution as a guide, about $2.15 could be saved on the 12,000,000 eligible prescriptions in the non-Drug Benefit market for a total annual saving of $25,800,00. Since product substitution is practised on only about 15% of these, or 1,800,000 prescriptions, and since mandatory price substitution is not the rule on these prescriptions, the actual savings are certainly no more than $4,000,000 and likely much less [1984, 43-44].

This is consistent with Gorecki [1986*a*, Table 5, 388] who shows that in 1983, for seven high-volume interchangeable drugs, the mean market share of the generic drug manufacturers – whose drugs are typically lower-priced – was 26.05 per cent for one private third-party drug program in Ontario, but 78.20 per cent for the ODB.

It also appears that the dispensing fee was somewhat higher in the non-ODB market, although to what extent is not known with any accuracy. Irrespective of whether the fee was higher in the non-ODB market, there is evidence to suggest that ODB interventions may have made it higher than it need be. In 1979, the ODB raised its dispensing fee by $0.22 to compensate pharmacists for income lost because of the elimination of the spread on selected high-volume drugs. Since drug utilization patterns in the ODB and non-ODB markets are different, prices would have to be reduced on a different set of high-volume drugs in order for private drug plans to increase their fee by $0.22. One plan that attempted this and other cost-cutting moves was successfully boycotted by pharmacies and had to agree to the fee increase with reduced prices on the same drugs as within the ODB.[21] Thus a sensible ODB policy to reduce the price-spread inadvertently had an adverse effect on private third-party drug programs. The possibility therefore arises that the provincial government placed greater emphasis on its role as a payer under the ODB than as regulator of the Ontario drug market for the benefit of all Ontarians.

The Solution: Bills 54 and 55

Bills 54 and 55 were proclaimed in December 1986 as the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act. Considerable changes were made to the proposed legislation introduced on 22 April 1986. The original bills gave considerable authority to the government of the day. For example, explanatory notes to Bill 54 said:

> The Act gives broad discretion to the Lieutenant Governor in Council to make regulations concerning,
> a) what prescription drugs and substances are to be listed under the Act;
> b) who is to be eligible for benefits under the Act;
> c) how much the Minister will pay for the supplying of drugs and substances under the Act; and
> d) what charges, if any, may be made directly to eligible persons.

In the law as it was passed, the discretion of the Lieutenant Governor in Council was considerably reduced by specifying in legislation what would have been in the regulations. It appears, however, that the government only accepted these changes – reluctantly – as a result of pressure from several groups, particularly pharmacists. In addition, the government was in a minority position.[22]

The Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act were aimed at "ensuring realistic drug prices for all Ontarians, sound management of the government drug benefit program, and consumer protection" [Ontario Ministry of Health 1985*b*, 1]. They implemented many, but by no means all, of the recommendations of the Gordon commission and even some of the Bailey committee. As such they attempted to deal with the vexing questions of selecting "realistic" drug prices, determining the dispensing fee, the length of treatment that should be dispensed at one time, and instituting product selection rules in the non-ODB market.

The Prescription Drug Cost Regulation Act – based on an amended version of Section 155 of the Health Disciplines Act – sets certain market-wide rules, while the Ontario Drug Benefit Act sets the legal framework for the ODB segment of the Ontario retail drug market. The ODB was originally established under the Ministry of Health Act of 1972, rather than under specific program-related legislation. These 1986 laws have a number of common features; for example, they both define "drug cost" in the same way. But there are also some marked differences; for example, how the dispensing fee is determined and the price selection rules they establish for interchangeable pharmaceutical products.

The Ontario Drug Benefit Act

Under this act and regulations pursuant to it, payment by the provincial government of pharmacists' claims was broken down into three parts:

- A fixed maximum dispensing fee, paid to pharmacists for the tasks of actually handling or making up the drugs for patients, together with any associated professional services, upon presentation of the prescription. Pharmacists are required to dispense the whole quantity.[23] An elaborate negotiating framework and procedures for determining the fee – involving both the Ontario Pharmacists' Association and the Ministry of Health – are outlined in the legislation.

The legislation provides that different fees can be charged by different classes of pharmacies.

- The cost of the drug was established according to the concept of the best available price (BAP). This was to be the lower of the manufacturer's price to the wholesaler and the pharmacist. The BAP is defined as the lowest amount, per unit of a particular brand of a drug, by dosage form and strength, that "can be purchased in Canada for wholesale or retail sale in Ontario" (Section 18 (4)).[24] This has been interpreted by the ministry as the price based on the package size that the vast majority of pharmacists in Ontario can purchase. The legislation gave the ministry considerable discretion in setting the BAP. It did not have to rely solely on the submissions of the manufacturers, but it could also use other information available to the ministry.[25] Finally, the ministry was given power to search manufacturers', wholesalers', and pharmacists' premises to make sure they were complying with the act – by, for example, providing accurate price data. In the event of a contravention by a manufacturer, the Lieutenant Governor in Council can refuse to designate the product concerned as a listed drug or remove that designation (Section 16 (2)).

- A fixed percentage margin of between 10 and 20 per cent could be added to the BAP. It was subsequently set at 10 per cent, where it remains today. Prior to these two acts, if a drug was distributed by a wholesaler, a 10-per-cent margin was added to the manufacturer's price; if more than 50 per cent of the drug was distributed directly by the manufacturer or via an agent, no margin was added. This legislation extended the 10-per-cent margin to all drugs that were distributed directly or through an agent. It is clear that those who drafted the legislation realized what they were doing in including this in the legislation and also realized that the Minister of Health was not in favour of such a measure.[26] The measure seems to have been motivated by a concern that small pharmacies might not be able to purchase at the BAP and that the 10 per cent provided an extra degree of protection.[27] The provisions for the establishment of different classes of pharmacies would have permitted a higher dispensing fee to be paid to smaller pharmacies. This might have been a cost-effective solution; indeed, the ministry proposed such a measure in 1987, but the OPA rejected it [Ontario Ministry of Health 1987*a*, 17-18].

The formulary lists all drugs that are eligible for reimbursement under the ODB together with the BAP and the size of the margin. Where several brands of the same drug are certified as interchangeable and appear together in the formulary's listing by therapeutic classification, only the lowest BAP is printed. In the January 1989 formulary, for example, the following appears for diazepam 10-mg tablets:

Drug identification number	Brand name	Firm name	BAP
013285	Valium	HLR	0.0050
013765	Vivol	HOR	
272442	Novodipam	NOP	
280429	E-Pam	ICN	
362158	Apo-Diazepam	APX	
396230	Diazepam	DTC	

Source Ontario Ministry of Health [1989a, 62].

No matter which brand is dispensed, the ODB will only reimburse pharmacists up to this BAP plus 10 per cent. However, all drug products are listed alphabetically by brand name at the back of the formulary together with the BAP of each product.

The Prescription Drug Cost Regulation Act

In the non-ODB market there are a variety of methods by which people pay for drugs. Probably the majority of people are included under a third-party program, which may be a benefit negotiated as part of a collective agreement or paid for separately through private insurance. Recent estimates suggest that approximately 80 per cent of those not eligible for ODB are covered by some sort of third-party coverage [Gordon 1984, 33; Hurley 1989, 26, 39].

The Prescription Drug Cost Regulation Act requires pharmacists to "set a single specific amount as a usual and customary dispensing fee" and post it "clearly and prominently in or adjacent to the dispensary area so that it is readable by the person presenting a prescription."[28] The fee has to be filed with the Registrar of the College of Pharmacists and may only be changed by notifying the registrar. The act is somewhat ambiguous about when more or less than the usual and customary fee can be charged, apart from where certain extra services are supplied, such as home delivery. It would appear that the usual and customary fee *must* be charged for dispensing an interchangeable drug, although in some instances the fee can be different.[29] Clearly, if this became commonplace the usual and customary fee would have to change. For single-source or noninterchangeable drugs a different fee may be charged, but if a higher fee is used it must be explained to patients.[30] One instance where the fee is typically lower is birth-control pills. In the non-ODB market, as in the ODB, the full quantity of the prescription has to be dispensed at one time, subject to some safeguards.

In the non-ODB market there is no elaborate formal mechanism for setting the fee. Pharmacists set their own fees. It should be noted, however, that professional statutes severely restrict competition between pharmacies with respect to advertising in the media.[31] There is no legislative requirement that the usual and customary fee bear any relationship to the ODB's negotiated fee except that under the ODB the ministry would reimburse the usual and customary fee if it were lower than the negotiated fee.

In the non-ODB market, drug cost is defined as the BAP plus, of course, the fixed 10-per-cent mark-up. However, pricing and product selection rules for interchangeable products in the two market sectors differ. Under the ODB, no matter which interchangeable product is dispensed, the pharmacist is reimbursed for the lowest-priced brand only – the BAP listed in the formulary. The legislation specifies that in the non-ODB market pharmacists can charge no more than the BAP "that is the lowest among the products in the person's inventory that are interchangeable with the product supplied."[32] In other words, whether or not product selection takes place, this is the maximum price that can be charged for the drug. There are some exceptions. If the consumer requests a particular product then the BAP for that product is charged. If the physician specifies no substitution then the BAP for that brand is charged.[33] Thus the drug cost portion of a non-ODB prescription for an interchangeable product varies depending upon the preferences of the physician and the consumer, as well as on the lowest BAP carried in the pharmacist's inventory.

The Influence of the Bailey Committee and the Gordon Commission

The Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act incorporated many of the suggestions made in the Bailey and Gordon reports of 1978 and 1984. The idea of the best available price had its genesis in the Gordon commission. Its aim was to make formulary prices more "realistic," or closer to actual transaction prices. The ministry was given some discretion in setting the BAP, and also power to inspect company records to determine the veracity of the price data submitted. Bailey's suggestion that only one price be printed for a group of interchangeable pharmaceutical products was adopted.

The 10-per-cent fixed margin on top of the BAP for wholesaling was not consistent with the suggestions of either Bailey or Gordon. It resulted in a windfall gain to pharmacists from the ODB of about $14 million or about $7 thousand per pharmacy in 1987.[34] To the extent that formulary prices and the 10-per-cent margin were followed in the non-ODB market, this probably increased the total windfall by as much again. Thus pharmacists received compensation approximately equal to the amount by which the BAP reduced the spread.[35] As such it is inconsistent with the spirit, if not the letter, of the Gordon commission's recommendations [1984, 82].[36]

In several important respects the 1986 legislation departed from the recommendations of both committees. On the question of interchangeability, Gordon had recommended that when pharmacists selected a brand different from that prescribed, they only be required to dispense a lower-priced brand, rather than no more than the lowest-priced interchangeable product in their inventory. The 1986 legislation left pharmacists free to decide whether to product select or not, but it *required* that they charge no more for the product than the lowest interchangeable BAP in their inventory.

Both Bailey and Gordon recommended that a copayment be introduced to make ODB recipients more cost conscious. Although the Ontario Drug Benefit Act allows for this specifically – Section 18 (1)(e) gives the Lieutenant Governor in Council the power to authorize a pharmacy to charge those eligible under the ODB a fee when supplying a listed drug – it has not been implemented. The elaborate fee-negotiating mechanism introduced under the Ontario Drug Benefit Act, was also a departure from the recommendations of both Bailey and Gordon. It gave a considerable role to the Ontario Pharmacists' Association, which, it could be argued, substantially limits the options of the Ontario government in setting dispensing fees.

The requirement that pharmacists dispense the whole or entire drug quantity as written, introduced under the Ontario Drug Benefit Act, was recommended by several reports, including the Gordon and Bailey reports. The Prescription Drug Cost Regulation Act permitted pharmacists to charge their usual and customary dispensing fees when undertaking product selection, rather than the lower PARCOST regulated fees, thus replacing Section 155 of the Health Disciplines Act. Indeed, the 1986 legislation sounded the death knell of PARCOST. Finally, the legislation was influenced by Gordon and Bailey in that it required that the consumer be provided with more information concerning drug costs and fees to provide them with a rational basis upon which to choose drugs. The legislation required that the prescription cost be broken down into the dispensing fee and ingredient cost, and that pharmacists post their usual and customary fees as well as information about the availability of lower-priced interchangeable pharmaceutical products in the dispensary area.

Developments since 1986

So far we have exclusively focused on the origins, evolution, and rationale for government intervention in the Ontario retail drug market with respect to the provision of drugs to certain eligible groups and setting drug prices and dispensing fees in both the public and private sectors. We have not examined drug therapy or consumption and prescribing patterns. These issues were not prominent on the health-care agenda in the 1970s and 1980s, but they have become more so in the last few years.

Attention was focused on the quality of drug care in Ontario by the release in 1987 of a review of the literature on drug utilization [Carruthers et al., 1987] and then the resignation in January 1988 of the chairman of the Drug Quality and Therapeutics Committee. The reason he gave for his resignation was "a continuing sense of frustration and dissatisfaction with a process which limits the effectiveness of the . . . [committee] in issues such as the pattern of drug utilization, the effectiveness of drug use and the spiralling costs of medications."[37] In 1989 the government of Ontario sponsored the International Conference on Quality Assurance and Effectiveness in Health Care. It was the opinion of one of the leading participants that in the 1990s health care will be dominated "by efforts to improve the accountability of our system through improved quality assurance . . . and evaluation of our health care activities" [Ontario Ministry of Health 1990*d*, 9-10].

Concern over the quality of drug therapy in Ontario and continuing difficulties with respect to the ODB as a result of the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act led to the creation in March 1988 of the Pharmaceutical Inquiry of Ontario. It had wide-ranging terms of reference and published several interim reports; the final report appeared in 1990. In the next four chapters, therefore, in addition to considering how successful the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act have been in resolving the various problems discussed in this chapter, we will devote some attention to the issue of quality assurance.

4 Dispensing Fees, Professional Services, and Patient/Consumer Copayments

One of the instruments that provincial governments have commonly deployed to contain the costs of their drug plans is patient/consumer copayments. In effect, public expenditure is being reduced by shifting the burden of funding, partially at least, back to the private sector, which in this case is the patient/consumer. There are, however, other impacts of copayment. Depending on the level of the copayment and how it is structured, it can affect the overall level of societal resources devoted to the dispensing function and the efficiency with which those resources are allocated. In addition, copayment can affect the demand for drugs, and thus patient/consumer well-being.

There are a variety of provincial copayment formulas (see Figure 1-4 on page 6):

- Pharmacists set their own dispensing fees and the patient/consumer pays a fixed percentage of that fee. In British Columbia the patient/consumer copayment is 75 per cent for those aged 65 and over up to a maximum of $125 per year. In Newfoundland it is 100 per cent for those aged 65 and over and receiving the Guaranteed Income Supplement, with no maximum.

- Pharmacists and the provincial government negotiate the dispensing fee and the patient/consumer pays a fixed dollar amount per prescription. In New Brunswick, certain beneficiaries paid $6.34 per prescription to a maximum of $120 per year.

- The provincial government and pharmacists negotiate a dispensing fee and the patient/consumer pays a maximum fixed dollar amount per prescription, but the pharmacist can discount the copayment to the patient/consumer. Such a system existed for many years in Saskatchewan.[1]

In several provinces, for example, Alberta and Saskatchewan, the copayment is related to the total cost of the prescription, which includes both the dispensing fee and drug cost.

Some provinces, notably Ontario and Quebec, have no copayment charges. However, as noted in Chapter 3, several reports commissioned by the government of Ontario in the late 1970s and early 1980s recommended fixed dollar patient/consumer copayments. Recently the Pharmaceutical Inquiry of Ontario recommended a fixed copayment of $4, to a maximum of $250 per patient/consumer per year [1990*a*, 156]. The inquiry did not, however, give any reasons in its report as to why this form of copayment was the most appropriate.[2]

Although Ontario does not have patient/consumer copayment, it does – like virtually all other provinces – negotiate the dispensing fee with the provincial pharmacy association. The patient/consumer copayment can, then, be viewed as a decision as to how much of the fee should be paid by the public sector and how much by the patient/consumer.[3] Thus, in considering the issue of patient/consumer copayment, attention needs to be paid not only to the implications of each copayment option for the split between the public and private sectors, but also the way in which the fee is set and any interaction between the fee and copayment.

The procedures by which the dispensing fee is set in Ontario – its level and the length of course of treatment for which a single fee should apply – are set out in the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act of 1986. In this chapter, we outline this process and then attempt to answer the following questions:

- Has the legislation been successful in its declared objective of increasing quantity dispensed per fee?

- Does the fact that the ODB fee is markedly lower than that charged in the non-ODB market suggest that the private sector is subsidizing the public sector?

- Is the current procedure for setting the ODB and non-ODB fees appropriate?

Each of these questions is discussed in detail; in doing so, considerable attention is also paid to other provinces.

The results indicate that the quantities dispensed per fee have not increased, and that the private sector is not subsidizing the public sector. There are numerous shortcomings in the current fee-setting procedures. The alternative favoured here is a market-based, competitively set dispensing fee, and a copayment set as a fixed percentage of the dispensing fee. This has the advantage of both stimulating

competition and extracting governments from direct involvement in the fee-setting process. Furthermore, it is likely to have a minimal impact on patient/consumer drug utilization (an issue discussed in Chapter 7).

Setting the Dispensing Fee

The dispensing fee under the ODB is a set amount per prescription dispensed that does not vary according to the price or the cost of the drug, whether it is interchangeable or not, or any of the characteristics of a pharmacy such as size, location, or cost.[4] Furthermore, the fee does not vary according to the standard of professional services offered by the pharmacists (e.g., whether they keep patient records or provide advice), which is an indication of the incomplete nature of the contract between the ODB and the pharmacists.[5] At the minimum, the ODB requires only that the pharmacist dispense the prescription as written, perhaps adding a few brightly coloured labels concerning directions for use; and, at the maximum, it requires carefully checking the prescription against the patient/consumer drug regimen, ensuring patient/consumer compliance, and giving verbal advice concerning the use of the drug (such as indicating possible side effects).

Dispensing is the product-oriented task of filling a prescription.[6] The pharmacist has to interpret and evaluate the prescription for correctness and completeness and verify its authenticity and appropriateness. Preparing the prescribed medication "involves selection of the appropriate product and ensuring that it is dispensed in accordance with requirements of the prescriber, the needs of the patient and legal considerations" [Pharmaceutical Inquiry of Ontario 1989*b*, 3]. Dispensing is frequently conducted in part by pharmacy technicians under the supervision of a pharmacist.

Professional services are the patient-oriented services such as "the establishment of patient medication files, professional consultation and health care services information" (Prescription Drug Cost Regulation Act of 1986, Ontario Regulation 691/86, Sections 2 (2) and 3 (i-iii)). Patient medication files can be established, for example, to monitor drug therapy and patient compliance.

The relative importance of the dispensing and professional-service roles were assessed as follows by the Pharmaceutical Inquiry of Ontario:

> At the present, the majority of patients view pharmaceutical services primarily as product-oriented. The emphasis, therefore, is on obtaining from the pharmacist the correct drug in the proper strength, dosage form and quantity, along with instructions for use [1989*b*, 4].

This is consistent with Ontario pharmacists' own evaluation of how they allocate their time – 55.3 per cent on dispensing and 11.7 per cent on professional and related services [Cockerill and Williams 1989, Table C4-5]. The dominance of the dispensing function is a theme of several reports on pharmacy in Ontario and Canada dating back to the 1960s, and in the United States [Cureton and Jay 1990, 1-3; United States Department of Health and Human Services 1990*a*, 8-9].

In view of the dominance of the dispensing compared to the professional-service component, we use the term dispensing fee to include professional services, as does the 1986 legislation relating to both the ODB and non-ODB markets.

Under the Ontario Drug Benefit Act the number of dispensing fees charged per prescription varies according to the length of time of the course of treatment. The schedule is as follows:

	Number of dispensing fees
Number of days of course of treatment	
0-100	1
101-150	1 1/3
151-200	1 2/3
201-250	2

where 250 is the maximum number of days' supply that can be prescribed and dispensed on a single prescription at one time.[7] It is not at all clear how this schedule was derived.

Under the dispense-as-written policy introduced in 1986, the pharmacist has to dispense the entire quantity prescribed, subject to this fee schedule and maximum. The legislation contains certain conditions under which less than the full amount can be dispensed at one time, including "if the proper exercise of professional judgement by the dispenser so requires" (Prescription Drug Cost Regulation Act of 1986, Ontario Regulation 691/86, Section 3 (a)). The policy objective was to eliminate the clause in the Participation Agreement under which pharmacists charged a separate dispensing fee for each monthly course of treatment supplied, even though the prescription might have been for, say, 100 days (see Chapter 3).

Institutional Framework

Since the establishment of the ODB, the dispensing fee has been negotiated between the Ontario Pharmacists' Association (OPA) and the Ministry of Health. In the past, reaching an agreement over the appropriate dispensing fee has often proved a long and protracted affair. In order to ameliorate these difficulties, the Fee Negotiating Committee (FNC) was established in 1986 under the Ontario Drug Benefit Act as a forum through which to negotiate, with the chairman acting as an arbitrator in the event of an impasse. The composition and role of the FNC and the procedure used is presented in Figure 4-1. It could be argued that this procedure was introduced in order to reduce the broad discretionary powers that the original Bill 54 had sought to give the government in setting the fee.

In 1987 and 1988 the parties resorted to the FNC to negotiate the fee, and even then they reached an impasse.[8] In these cases the OPA requested that the chairman recommend a fee. However, in the following round of negotiations the two sides reached an agreement without resorting to the FNC. Despite these procedures, however, the OPA and the ministry are still frequently very wide apart. For example, in 1988 the OPA felt an appropriate fee would be $7.21, the ministry $5.95 [Ontario Pharmacists' Association 1988*a*, 2; Ontario Ministry of Health 1988*b*, 22]. The eventual compromise was $6.22. In 1991, the parties resorted again to the FNC and reached an impasse. The Ministry of Health rejected the chairman's recommendation of a 6.1-per-cent increase and imposed a unilateral fee freeze effective on 1 December 1990 to 31 March 1992.

Determination of the Fee

While these procedures have not resolved the issue of the appropriate dispensing fee, some progress has been made towards the approach to be used in determining that fee. The chairman, in his first report, outlined the following possible approaches that had been discussed by the Fee Negotiating Committee:[9]

- Historic — The OPA proposed that the dispensing fee and the previous "spread" on drug prices (i.e., prior to the passage of the 1986 legislation) be combined to make up the dispensing fee. This would minimize the financial hardship imposed by the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act, particularly the dispense-as-written policy and the elimination of the spread.

- Extrapolation — Under this approach some previous dispensing fee would be adopted. The consumer price index or some variant that reflected the major cost components of pharmacy would then be applied to this base level to derive the fee.

- Interjurisdictional comparison — The fee would be set at that prevailing in jurisdictions elsewhere in Canada or in other countries. It was suggested that some adjustments or corrections – for example, for the volume of business – might be necessary to ensure proper comparisons. It might also have to be corrected to take into account the average length of treatment per fee.

- Market — Under this approach some weighted average of the dispensing fees in the non-ODB drug market would be used. This could include the pharmacists' usual and customary fee and that established by third-party carriers such as Green Shield. However, it should be noted that the Green Shield fee is based upon the usual and customary fee charged by the pharmacist.

- Economic or rational cost build-up — This approach, suggested by the OPA, is essentially to estimate the costs of dispensing. The major cost items of pharmacy would be determined by store and by prescription.

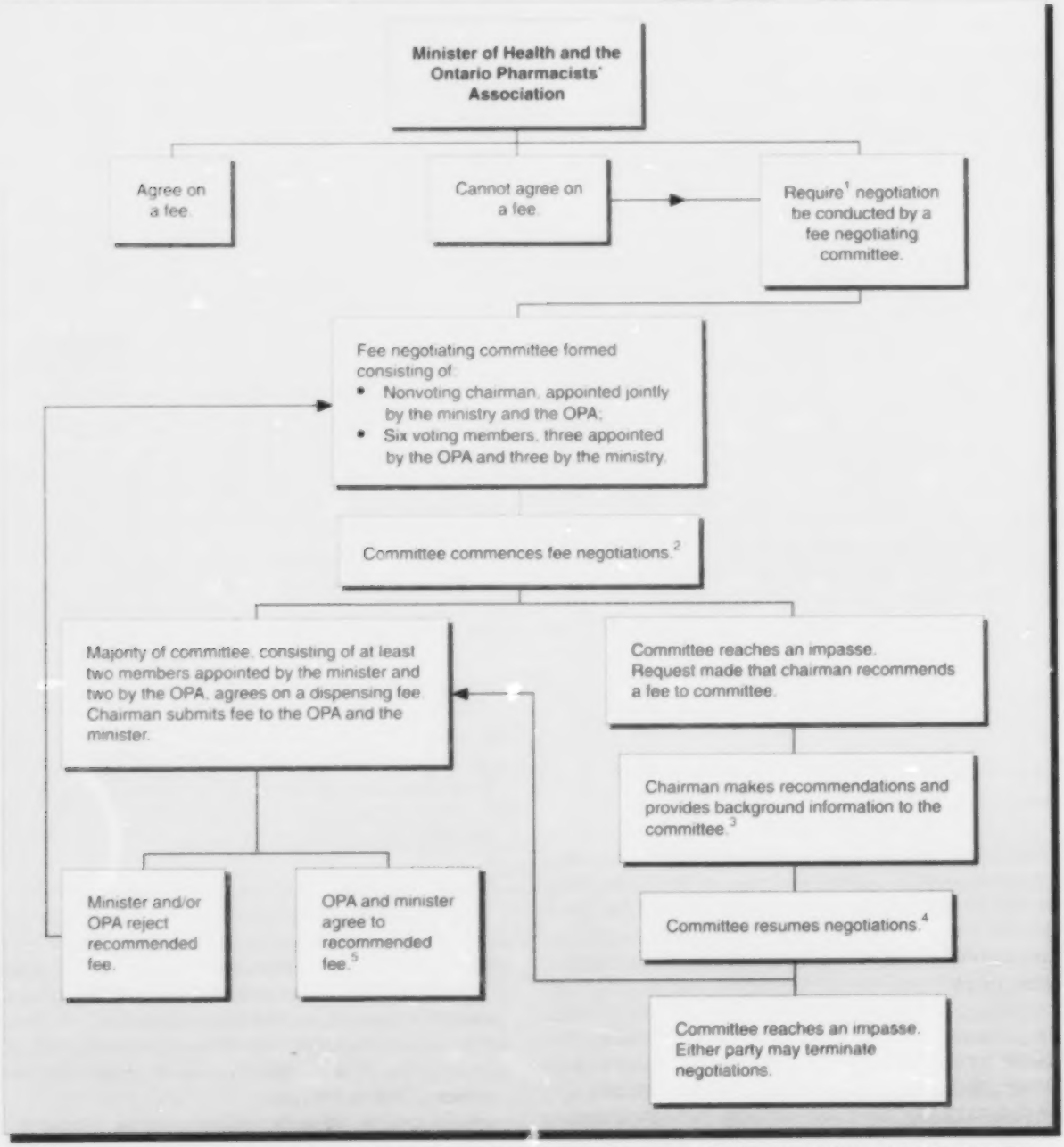
In evaluating these approaches, the chairman suggested that the basic principle would be "to determine as objectively as possible the actual expenses associated with dispensing prescriptions including a reasonable rate of return for capital" [Gordon 1987, 3]. The chairman rejected the first three approaches without stating a reason, discarded the fourth on the grounds that different dispensing fees in the non-ODB market signalled the existence of market imperfections, and accepted the last approach. This approach was favoured because "in principle it addresses the objective of determining a fee which covers the actual cost of dispensing a prescription" [Gordon 1987, 5].

The chairman's report of 1987 set the framework within which dispensing fee negotiations have taken place. In that report the chairman listed four major cost components of pharmacy: 1) the wages of pharmacy personnel relating to dispensing; 2) rent, utilities, and maintenance; 3) costs such as administration, taxes, licences, professional services, insurance, and marketing; and 4) a reasonable rate of return for the capital invested in fixed assets, receivables, and inventory [Gordon 1987, 6].

The chairman suggested 15 per cent as a reasonable rate of return. Taking into account costs, and based on 40,000 prescriptions a year, the chairman recommended a fee of $5.95. In 1988 the chairman recommended a fee of $6.22, "made up of a base of $5.95 . . . plus an increase of 4.5 per cent." This latter figure was "based primarily on government

Figure 4-1

How pharmacists' dispensing fees are determined under the Ontario Drug Benefit Act of 1986


Minister of Health and the Ontario Pharmacists' Association
Agree on a fee.
Cannot agree on a fee.
Require[1] negotiation be conducted by a fee negotiating committee.
Fee negotiating committee formed consisting of:
• Nonvoting chairman, appointed jointly by the ministry and the OPA;
• Six voting members, three appointed by the OPA and three by the ministry.
Committee commences fee negotiations.[2]
Majority of committee, consisting of at least two members appointed by the minister and two by the OPA, agrees on a dispensing fee. Chairman submits fee to the OPA and the minister.
Committee reaches an impasse. Request made that chairman recommends a fee to committee.
Chairman makes recommendations and provides background information to the committee.[3]
Minister and/or OPA reject recommended fee.
OPA and minister agree to recommended fee.[5]
Committee resumes negotiations.[4]
Committee reaches an impasse. Either party may terminate negotiations.

1 The minister or the OPA may, by notice in writing to the other, require the formation of the committee. After the notice has been received, the committee must be formed within seven days.
2 As soon as reasonably possible on a date set by the chairman.
3 The chairman must make the recommendation within 30 days of being requested to do so.
4 Within seven days of receiving the chairman's recommendations.
5 Reply must be made within 14 days of receiving recommendation.

SOURCE Ontario Drug Benefit Act, 1986, Section 7.

guidelines for increases in other sectors which are dominated by government expenditures" [Gordon 1988, 3].

While the chairman's report set out a framework that was acceptable to both the ministry and the OPA, much remains to be done to flesh it out. To this end, the chairman proposed that a study of the costs of dispensing a prescription be carried out. In the words of the chairman:

> The objective of a joint cost study should be to determine a reasonable and agreed upon estimate of the cost of dispensing a prescription in an average sized (volume) pharmacy operating in Ontario. This agreed upon cost of dispensing should not necessarily be the final dispensing fee but rather the basis for negotiations between the Ministry of Health and the Ontario Pharmacists' Association which would be the ultimate determinant of the dispensing fee. The final fee as opposed to the dispensing cost may contain elements of political policy in addition to simple reimbursement for services provided. It should not be the intent of the joint cost study to be involved directly in political policy but rather to determine a reasonable estimate of the cost of dispensing [Gordon 1988, 4].

The phrase "elements of political policy" is somewhat nebulous. One interpretation is that it refers to the relative bargaining strengths of the Ministry of Health and the OPA.

Although the chairman has been calling for a joint study of this kind for several years, the ministry and the OPA have failed to agree upon an approach to conducting it [Ontario Ministry of Health 1988*b*, 7]. The major differences seem to be about appropriate benchmarks, methods, and study objectives [Ontario Pharmacists' Association 1988*a*; Ontario Ministry of Health 1988*b*; Gordon 1988]. Thus five years after the passage of the Ontario Drug Benefit Act in 1986 and seven years after the chairman of the FNC first made his suggestions as to the determination of the dispensing fee, the problem seems as intractable as ever.

The Impact of the 1986 Legislation on Quantity Dispensed

The length of the course of treatment prescribed by a physician usually depends on the total quantity prescribed and the daily dosage.[10] Before the 1986 legislation, under the Participation Agreement between pharmacists and the Ministry of Health, it was agreed that "the quantity of a drug to be provided . . . shall be sufficient for one month's course of treatment, except where the course of treatment is less than one month, in which case the quantity provided shall be sufficient for the course of treatment." Pharmacists received only one dispensing fee per month's supply per patient for certain drugs – designated in the formulary by a circle containing the number "1" – even if the pharmacist submitted more than one claim per patient per drug. These so-called circle one drugs were generally for longer-term therapies, where at least one month's supply could be safely prescribed.[11]

Under the Ontario Drug Benefit Act, the circle one designation disappeared from the formulary and the Participation Agreement contained no reference to the length of the course of treatment.[12] Instead, a dispense-as-written policy was legislated. In other words, if a prescription was for 90 days, the patient would make one visit for a 90-day supply and the ODB would be billed for one dispensing fee. If, however, the physician decided to write six prescriptions for a 15-day supply each, then the ODB would pay six fees.

In a study undertaken for the Ministry of Health and the OPA in 1981, Woods Gordon examined the possible short-term and long-term impacts of introducing a dispense-as-written policy. In the short term (four to six months), the study predicted, there would be a reduction in overall ODB claims of 3.3 per cent, where for each claim one dispensing fee is paid. In the long term, physicians' prescribing habits would change. The experience of B.C. Pharmacare was taken as a benchmark for the longer-term impact, since under this program pharmacists could dispense up to a 100-day supply per claim. Based on a comparison of average quantities dispensed per claim for 100 drugs in British Columbia and Ontario, Woods Gordon estimated that there would be "a net reduction in ODB claims of 14% . . . over a one to two year period" [1981, vol. 1, 6].

The Result: No Change in Quantity Dispensed

In order to estimate the impact of the 1986 dispense-as-written policy in Ontario, we analysed the average quantity dispensed per claim and the number of claims per drug for a sample of 40 high-volume, circle one drugs over the period 1986-89 (Table 4-1). In March 1986 these 40 drugs accounted for approximately one third of all ODB claims.[13] If Woods Gordon is correct, the number of claims should have decreased and the average quantity dispensed per claim increased. However, their estimate was probably a lower bound – the upper bound being a threefold increase in average quantity dispensed and a two-thirds decrease in the number of claims. This assumes, of course, that a 100-day supply is appropriate in all cases.

In assessing the impact of the dispense-as-written policy we will concentrate on the average quantity dispensed per claim, rather than the number of claims (Table 4-2). There were quite dramatic changes in the number of claims per drug, which may not be attributable to the dispense-as-

Table 4-1

Number of claims[1] and average quantity dispensed per claim for 40 high-volume drugs under the Ontario Drug Benefit, before and after the introduction of a dispense-as-written policy, 1986-89[2]

	Pre-policy, 1986		Post-policy					
			1987		1988		1989	
Drug, strength, and dosage form	Number of claims	Average quantity dispensed (Number of tablets, capsules, etc.)	Number of claims	Average quantity dispensed (Number of tablets, capsules, etc.)	Number of claims	Average quantity dispensed (Number of tablets, capsules, etc.)	Number of claims	Average quantity dispensed (Number of tablets, capsules, etc.)
digoxin 0.25-mg tablet	32,109	32.17	30,868	33.03	30,355	34.31	27,259	35.40
digoxin 0.125-mg tablet	60,865	32.22	62,236	32.50	63,383	33.30	58,414	34.16
propranolol 40-mg tablet	21,794	81.81	19,348	81.96	17,932	83.62	14,285	85.95
nifedipine 10-mg capsule	13,466	120.09	15,373	114.04	16,471	115.62	13,278	113.15
diltiazem HCl 60-mg tablet	6,176	115.59	10,786	113.36	17,162	114.84	19,393	113.67
diltiazem HCl 30-mg tablet	8,253	117.41	13,503	114.98	19,071	117.61	20,894	116.73
amiloride HCl and hydrochlorothiazide 5-mg and 50-mg tablet	24,122	33.75	29,006	34.35	30,939	35.61	28,593	36.51
methyldopa 250-mg tablet	20,394	74.48	19,254	75.04	17,958	77.13	14,390	78.86
hydrochlorothiazide and spironolactone 25-mg and 25-mg tablet	15,809	43.03	14,506	42.89	13,643	43.95	11,245	44.74
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	53,141	36.63	53,920	37.05	53,613	37.95	46,871	38.65
metoprolol tartrate 100-mg tablet	7,840	66.33	7,235	66.96	6,938	67.94	5,891	69.28
metoprolol tartrate 50-mg tablet	17,356	59.80	17,072	60.11	17,037	61.63	15,305	62.76
hydralazine HCl 25-mg tablet	7,233	85.58	7,270	85.21	6,991	86.35	5,519	86.83
prazosin HCl 1-mg tablet	7,321	62.74	7,397	65.22	7,146	66.42	6,076	68.21
isosorbide dinitrate 30-mg tablet	17,183	135.25	17,862	133.95	19,099	132.00	18,058	129.15
isosorbide dinitrate 10-mg tablet	15,538	132.97	15,336	133.24	15,812	132.52	14,436	131.82
acetylsalicylic acid 650-mg ent. tablet	41,538	88.24	44,165	86.18	47,278	85.31	41,713	85.73
acetylsalicylic acid 325-mg ent. tablet	21,496	79.34	26,915	74.07	37,044	68.64	46,393	63.06
naproxen 250-mg tablet	15,423	68.16	15,337	67.42	14,938	66.27	13,485	65.82
ibuprofen 400-mg tablet	7,507	86.88	7,705	85.34	7,776	83.93	7,434	81.50
diclofenac sodium 50-mg ent. tablet	10,475	75.94	12,505	75.25	12,634	74.77	12,999	73.50
ketoprofen 50-mg ent. tablet	6,045	85.97	7,287	85.12	6,596	87.14	5,115	84.04
phenytoin (diphenylhydaptoin) sodium 100-mg capsule	13,940	93.23	14,783	93.46	15,591	94.76	15,046	94.67
diazepam 10-mg tablet	24,798	56.59	24,125	55.56	24,366	55.24	21,576	54.55
lorazepam 1-mg tablet	22,193	53.72	26,061	53.22	30,318	52.98	31,130	51.90
triazolam 0.5-mg tablet[3]	18,980	32.95	21,374	33.36	23,247	33.51	...	...
triazolam 0.25-mg tablet	26,836	32.59	30,877	32.59	35,520	32.96	44,124	39.08
potassium chloride 8 mEq LA tablet	47,302	71.48	47,910	72.58	48,600	74.03	44,197	75.37
calcium carbonate 500-mg tablet	19,281	54.66	27,319	55.28	25,962	57.11	24,427	59.52

furosemide 40-mg tablet	48,999	43.15	51,398	43.85	54,479	45.19	52,124	46.38
hydrochlorothiazide 50-mg tablet	45,043	34.22	40,534	35.03	36,539	36.58	29,213	37.80
sulfinpyrazone 200-mg tablet	8,769	95.93	7,275	95.13	6,482	94.95	4,805	94.95
aluminum hydroxide and magnesium hydroxide 40-mg and 40-mg/ml O/L	15,154	692.88	15,661	670.60	16,611	660.58	15,793	655.59
cimetidine 300-mg tablet	18,709	87.74	16,586	87.89	15,143	87.36	12,159	87.98
lactulose 666.7 mg/ml O/L	4,248	935.56	5,364	904.36	6,414	894.42	6,883	847.62
metoclopramide HCl 10-mg tablet	6,520	84.25	5,450	83.71	4,699	84.29	3,965	84.09
glyburide 5-mg tablet	19,931	65.37	22,989	66.61	28,019	70.85	29,599	73.03
levothyroxine (sodium) 0.1-mg tablet	19,451	34.66	22,232	35.97	24,542	38.13	25,503	40.27
theophylline anhydrous 300-mg LA tablet	10,824	63.56	12,284	64.40	12,957	66.00	11,803	66.59
theophylline anhydrous 200-mg LA tablet	7,943	64.95	8,844	66.61	9,627	66.55	8,651	68.03
All ODB claims	2,393,727	25.16	2,602,422	26.13	2,955,546	31.82	2,895,094	30.65

1 Note that if a doctor's prescription is written for a 30-day course of treatment with five refills, this would be six claims.
2 Refers to March of each year.
3 This dosage form and strength was withdrawn from the 1989 formulary.
Source: Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1986-89.

Table 4-2

Level and ratios of the average quantity dispensed per ODB claim for 40 high-volume drugs, 1986-89

	Average quantity dispensed[1]		Standard deviation	
	Number = 39*	Number = 40**	Number = 39	Number = 40
1986	109.69	107.77	170.57	168.80
1987	108.05	106.19	164.51	162.82
1988	108.18	106.31	162.15	160.50
1989	107.10	...	155.57	...
	Ratio			
	Percentage change in average quantity dispensed[2]		Standard deviation	
	Number = 39	Number = 40	Number = 39	Number = 40
1987/86	–0.10	–0.07	2.23	2.21
1988/87	1.19	1.17	2.46	2.43
1989/88	0.88	...	3.95	...
1989/86	2.12	...	7.42	...

*Excludes triazolam 0.5-mg tablet, which was not in the January 1989 formulary.
**The full sample in Table 4-1.
1 The mean of the average quantity per drug presented in Table 4-1.
2 The mean of the change in average quantity per drug presented in Table 4-1.
SOURCE Derived from Table 4-1.

written policy. Furthermore, these changes are more dramatic over the longer period, thus obscuring the longer-run impact predicted by the Woods Gordon study.

In general, there was little change in the average quantity dispensed. If anything it decreased rather than increased. The sample average went from 107.8 in March 1986 to 106.2 in March 1987 to 106.3 in March 1988. One difficulty of using average quantity dispensed is that for some drugs it is very large, and changes in their quantities dispensed may overwhelm changes in quantities dispensed of drugs where the daily dosage is much lower. In order to take this into account, we also calculated the percentage changes. With this measure there was still little change, the average quantity dispensed increased by only 2.1 per cent between March 1986 and March 1989. Thus we can conclude that the dispense-as-written policy has had little measurable impact on the 40 to 50 per cent of the Ontario drug market accounted for by the ODB.

Why Was There No Change in Quantity Dispensed?

One of the important objectives of the 1986 legislation was to increase the quantity that is dispensed in a single transaction with the patient/consumer. Limiting the maximum quantity dispensed to that appropriate for a month's course of treatment was an historical anachronism, despite the gloss that has been subsequently introduced. As discussed in Chapter 3, there are good reasons why larger quantities can be dispensed at one time, subject, of course, to certain safeguards concerning the health of the patient/consumer.

There are a number of possible reasons why the dispense-as-written policy has had little or no impact on quantities dispensed. First, its implementation was faulty. There was no information campaign aimed at physicians and patient/consumers. Second, the incentives favoured the status quo prior to 1986; the legislative change did little or nothing to alter these incentives.

The practice of dispensing one month's supply at a time – in effect since the mid-1970s – was deeply engrained in the system. It probably influenced physicians to prescribe on a monthly basis. There was therefore almost certainly a considerable amount of inertia on the part of physicians to overcome. This inertia may have been compounded by the fact that larger quantities prescribed at one time would probably result in fewer patient/consumer visits to the physician and less income.[14]

There was also little incentive for pharmacists to replace multiple dispensing fees with a single fee for dispensing

the same amount of a drug [Ontario Pharmacists' Association 1986, 26-27]. Not only would this result in a direct loss of income, but also an indirect one in that the consumer would probably visit the pharmacy less frequently, and the pharmacist would lose business on nonpharmacy items.

Finally, ODB beneficiaries had little incentive to demand that, say, 100 days' worth of drugs be supplied at one time, apart from the convenience of fewer visits to the pharmacist. Since beneficiaries pay nothing towards the dispensing fee, there would be no reason for them to encourage either their physician to prescribe for longer periods or their pharmacist to dispense in greater quantities. In fact, consumers appear not to have even been aware of the policy change; the Ontario government made little attempt to inform them in the three years following the passage of the 1986 legislation. Furthermore, patients may well be unaware of the length of treatment prescribed, since in the ODB market approximately 50 per cent of all new prescriptions are verbal [Woods Gordon 1981, vol. 1, 3].[15]

A Successful Dispense-as-Written Policy: B.C. Pharmacare

In order to estimate the impact of a successful dispense-as-written policy, and whether it would be worthwhile for the Ministry of Health to introduce policies to overcome the inertia of physicians, pharmacists, and patient-consumers, we examined the experience of senior citizens under B.C. Pharmacare for the first quarter of 1986 and 1987. We selected this program and this period for several reasons:

- B.C. Pharmacare was used earlier as a benchmark by Woods Gordon in their 1981 study.

- In the first quarter of 1986 and 1987, B.C. Pharmacare resembled the ODB in one important respect – senior citizens received all their medication and dispensing services free of charge. However, B.C. Pharmacare has always allowed up to 100 days' supply to be dispensed for one dispensing fee (even for patient/consumers on welfare). Nevertheless, there have been periodic pressures to dispense smaller quantities more frequently.[16]

- In contrast with Ontario, British Columbia conducts drug utilization reviews and competency tests among pharmacists. As a result, the standard of prescribing and dispensing practices with respect to quantity in British Columbia should be as good, if not better, than in Ontario.[17]

Using 35 of the 40 high-volume drugs shown in Table 4-1 as the sample, we estimated the ratio between the average quantities dispensed per claim in British Columbia and Ontario.[18] The B.C. sample consisted of individuals aged 65 and over, and the Ontario sample consisted of all those covered by the ODB, a group dominated by persons aged 65 and over (see Table 2-2 for a breakdown of the ODB beneficiaries by plan type). The mean and standard deviation of this ratio for 1986 and 1987 are presented in Table 4-3.

Table 4-3

A comparison of average quantity dispensed per claim of 35 high-volume drugs,[1] Ontario Drug Benefit[2] and B.C. Pharmacare,[3] before and after B.C. Pharmacare introduced a copayment on dispensing fees for seniors, 1986-89[4]

	Ratio of average quantity dispensed, B.C. Pharmacare to Ontario Drug Benefit			
	Before introduction of copayment		After introduction of copayment	
	1986	1987	1988	1989
Mean	1.4607	1.4734	1.6344	1.6302
Standard deviation	0.4435	0.4188	0.4060	0.3735

1 For each drug the average quantity dispensed per claim in British Columbia and Ontario is estimated separately. Then, for each drug the ratio of average B.C. quantity to average Ontario quantity is estimated. The table reports the mean of this ratio. The sample was the one in Table 4-1 excluding acetylsalicylic acid 325-mg ent. tablet, calcium carbonate 500-mg tablet, aluminum hydroxide and magnesium hydroxide 40-mg and 40-mg/ml O/L, and triazolam 0.5-mg tablet.
2 Refers to all claims paid for by the ODB.
3 Refers only to claims paid by Pharmacare for senior citizens.
4 For the ODB March of the given year; for B.C. Pharmacare the first quarter.
Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1986-89; and data supplied by B.C. Pharmacare.

The average quantity dispensed per claim was much greater in British Columbia than in Ontario – on average nearly 50 per cent greater. If the average course of treatment for Ontario was 30 days, then the average for British Columbia was 45 days.[19] Thus, if the same quantities were dispensed in Ontario as in British Columbia for these 35 drugs, total claims would fall by one third.[20] In Ontario approximately 70 per cent of claims were for maintenance therapies. If the results of the 35 drugs could be generalized to all maintenance drugs, there would be about a 20-per-cent reduction in ODB claims.[21] For 1987/88, this would have been worth $36.2 million in reduced claims, given that total fees in 1987/88 were $180.9 million (Table 2-5). These savings are substantial, and to the extent the same problem occurs in the non-ODB sector, the gains to the entire Ontario market would be even greater.

Policy Prescription

In order to successfully implement a policy to raise average quantities dispensed, it is necessary to communicate the policy to those concerned with its implementation, but also –and this is much more difficult – to change the incentives under which they operate. Some steps have recently been taken in this direction. In the summer of 1990 the Ministry of Health informed physicians in a *Bulletin* entitled "Prescription quantities," that under the Prescription Drug Cost Regulation Act "the pharmacist will dispense the entire quantity of the drug prescribed at one time."

It gave various situations where larger quantities could be dispensed at one time. In addition, for high-volume maintenance drugs, quantities could be suggested, together with conditions under which monitoring would be required.[22] The ministry also informed senior citizens of the 1986 legislation; for example, an article appeared in the summer 1990 issue of *Especially for Seniors*, a publication of the Ontario Advisory Council on Senior Citizens. The article was entitled "Prescribing for convenience and quantity." The opening sentence asked the question, "Did you know that it is no longer necessary for a physician to write a prescription in one-month quantities with repeats?"

Nevertheless, there is room for still more improvement. Pharmacists could be required to display, in a prominent place, a sign saying that the whole quantity prescribed is to be dispensed at one time unless it is the pharmacist's professional judgment that it should not be or the patient/consumer prefers other arrangements (e.g., because he/she does not have the necessary funds). If the pharmacist judged that the whole quantity should not be dispensed, this could be communicated to the patient/consumer. The sign could also state that a quantity sufficient for up to a 100-day course of treatment can be dispensed per dispensing fee.[23] In order to change the basic incentives under which physicians, pharmacists, and patient/consumers operate with respect to the quantity dispensed, a patient/consumer copayment could be introduced.[24] What kind of patient/consumer copayment is most appropriate is discussed extensively later in the chapter.

If the reasons outlined above as to why the 1986 dispense-as-written policy has had little effect are correct, then the recent changes are likely to lead to only a minor increase in quantity dispensed. The information campaign, although it is an essential first step, does not alter the incentives under which the pharmacist, physician, and patient/consumer operate. The argument for further action, such as a patient/consumer copayment, is therefore reinforced. The Ontario government seems to agree; in May 1991, it stated that for "well-stabilized ODB recipients on long-term courses of drug therapy, larger quantity prescribing will be enforced" [Ontario Ministry of Treasury and Economics 1991, 13]. However, no details of the enforcement mechanism were provided.

Public Parsimony at Private Expense?

Before we examine the extent of the differential between private-sector and public-sector fees, we will devote some attention to possible reasons why that differential exists. Markets for a product or service may be priced differently at the same or adjacent locations, provided that it is not profitable to arbitrage by buying in the cheaper market and reselling in the higher-priced market. In other words, prices may differ to the extent that this difference is just equal to the cost of arbitrage. If this cost is minimal, then prices for the service or product will be the same. In the dispensing service, it is clear that differences can exist between the ODB and non-ODB markets because arbitrage is not possible. In other words, if the ODB fee is $6.22 and the non-ODB fee is $8.49, the ODB patient/consumer cannot resell his/her $6.22 fee to a Green Shield customer. Indeed, the Green Shield or Blue Cross patient/consumer probably does not even know the ODB dispensing fee, since the pharmacy is not required to post it. Furthermore, to the extent that neither have a copayment, there is no incentive for such arbitrage to exist.

For there to be differences between the ODB and non-ODB dispensing fees, not only must the market be segmented, but there must be differences in demand and/or supply. On the demand side, the Ministry of Health acts as a buyer of dispensing services for its client population. At the present time, the ministry is concerned about the cost of the ODB and appears to be prepared to use its size in

the market to bargain very hard with the Ontario Pharmacists' Association to keep ODB fees down.

In the non-ODB market there is no group comparable in size to the Ministry of Health. Indeed, in one instance where a third-party program did attempt to negotiate in a determined fashion to rectify the adverse effects of government intervention, it was successfully boycotted by pharmacists.[25] The government did, however, through the Prescription Drug Cost Regulation Act, attempt to inject an element of competition in the non-ODB dispensing fee by requiring pharmacists to post fees for interchangeable drugs. As a result, consumers certainly seem to be aware of these prices [Ontario College of Pharmacists 1988, 6-7; and Ontario Ministry of Health 1987*a*, 15]. And Ontario residents who are not covered by the ODB or a private third-party plan are likely to be price-sensitive [Gordon 1984, 33; Hurley 1989, 39]. Even some of those who are covered by a drug plan may have an incentive to search for a lower-cost pharmacy if a copayment is required. Thus on the demand side it is not clear, a priori, whether prices in the two markets will be the same or different, since the element of competition introduced by the Prescription Drug Cost Regulation Act may be sufficient to match the bargaining strength of the ministry.

On the supply side, it is difficult to estimate whether the costs of dispensing an ODB prescription are greater or less than those of dispensing a non-ODB prescription. The Ministry of Health argues that because there are proportionately more renewals in the ODB market than in the non-ODB market, and since a renewal is less costly to dispense, the ODB fee should be lower [Ontario Ministry of Health 1988*b*, 18-21; Woods Gordon 1981, vol. 1, 4]. On the other hand, the ODB population are heavy users of drugs compared to the general population and are likely to require more professional services from the pharmacist, which partly offsets the lower dispensing cost.[26]

The ODB fee for all prescription drugs and the average, median, low, and high "usual and customary" fees charged by pharmacists for interchangeable drugs are presented in Table 4-4 for the period 1987-91. It is clear from these data that the average or median usual and customary fee in the private sector is always above the ODB fee. By the late 1980s, the median usual and customary fee was about one third more than the ODB fee. Also worth noting is that some pharmacies charged dispensing fees well below and above the ODB dispensing fee.

There are no guidelines or legislated limits to the fees that may be charged in the non-ODB market for noninterchangeable and single-source drugs. It appears, however, that the usual and customary fee is charged for both, with the notable exception of birth-control pills, for which a lower fee is often charged. A telephone survey of 13 Ottawa

Table 4-4

The structure of private and public dispensing fees in the retail drug market, Ontario, 1987-91

		Private[1]			
				Range	
	ODB[2]	Average	Median	Low	High
			(Dollars)		
24 March 1987	5.95	6.87	6.85	3.00	10.98
13 May 1987	5.95	7.02	7.00	3.00	10.98
15 September 1987	5.95	7.28	7.49	3.00	10.98
31 December 1987	6.22	7.37	7.25	3.49	9.99
27 May 1988	6.22	7.72	7.82	4.50	10.00
9 January 1989	6.22	8.02	7.99	4.80	10.00
11 July 1989	6.22	8.22	8.49	4.98	11.00
31 December 1989	6.44	8.44	8.49	4.98	11.00
1 June 1990	6.47	8.62	8.75	4.98	12.00
31 December 1990	6.47	8.94	8.99	4.98	12.00
1 June 1991	6.47	9.14	8.99	4.98	13.00

1 The usual and customary fee for interchangeable drug products.
2 ODB negotiated dispensing fee. It applies to all prescription drugs, single source or interchangeable. The average ODB dispensing appears to be slightly below the negotiated fee – less than 1 percentage point – for some periods.
Source Based on data supplied by the Ontario Ministry of Health and the Ontario College of Pharmacists.

pharmacists conducted by the author in November 1989, which included both chains and independents, revealed that while the usual and customary fee ranged from $6.75 to $9.49, the fee for birth-control pills ranged from $3.40 to $6.99.

The data in Table 4-4 suggest that the Ministry of Health as a bargainer is effective in obtaining, on average, lower dispensing fees than those prevalent in the private sector. The public-sector portion of the Ontario retail drug market is essentially a bilateral monopoly – controlled by the government of Ontario on one side and the OPA on the other – that is enshrined in legislation. The outcome of this market, in terms of fees, depends upon the relative bargaining strengths of the two parties. The fee will range between the maximum the ODB is prepared to pay and the minimum the OPA will accept. To the extent that the government has considerable power and influence and is concerned about the rising costs of the ODB, it is likely to bargain very hard to limit fee increases.[27]

The differences between ODB and non-ODB fees are comparable to the differences between health-care expenditure in Canada and the United States after 1971, when publicly funded health care was introduced in Canada [United States General Accounting Office 1991, Table 1.2, 15]. Provincial governments negotiated to restrain increases in physicians' fees, but in the United States there was no such large buyer, and prices went up at a faster rate [Barer et al. 1988, 4-5].

The private sector in the Ontario retail drug market resembles a monopolistically competitive market. Each pharmacy sets a dispensing fee depending upon a number of factors such as its size, location, average quantity dispensed per fee, the income level of its clients, its level of efficiency, the ratio of pharmacists to technicians, and the type of plan in which local patient/consumers are enrolled. Given that these factors vary by location within the province, private-sector fees are likely to vary. In terms of the mean level, several factors, including the lack of a bargaining agent like the government, the various restrictions on advertising fees, and the extensive drug plan coverage outside the ODB, result in a private-sector fee that is, on average, higher than the public-sector fee.

The government of Ontario has said that "there cannot be cost pressures in Pharmacy that justify such increases in [private sector] fees, particularly recognizing the increased volume in prescriptions that are being generated" [Ontario Ministry of Health 1988*b*, 20]. Thus, while posting the fees has undoubtedly made people more aware of fee levels and may have resulted in a lower usual and customary fee, the structures of the private and public retail drug markets in Ontario mean that fee differences are likely to persist.

This analysis suggests that if pharmacists are rational profit-maximizers they will set (or attempt to set) prices that achieve this objective. Different prices for the same service are perfectly consistent with this objective, reflecting the different economic conditions in each market. The policy that sets fees in the public sector does not have to result in higher private-sector fees.[28] Green Shield's view that the absence of an ODB fee increase "has caused pharmacists to recover their perceived income loss of fee income in ODB dispensing by an offsetting increase in posted fees for private sector dispensing" is therefore not necessarily correct [1988, 10]. This does not mean, of course, that the government of Ontario cannot introduce legislation that would alter the structure of the private retail drug market with a view to fee reduction – an issue discussed in the next section.

Determining the ODB Fee: Does the Process Work?

An ODB dispensing fee that is based on pharmacists' dispensing costs, including a reasonable rate of return, seems an eminently sensible approach. However, there are a number of difficulties with the cost-based method: first, how feasible is it to estimate pharmacy dispensing costs; and, second, what meaning can be attached to such numbers.

Can Pharmacy Dispensing Costs Be Estimated?

There are a number of conceptual and estimation problems in determining the costs of dispensing [Gordon 1987, 1988; Ontario Ministry of Health 1987*a*, 1988*b*]. The fact that the Ministry of Health and the Ontario Pharmacists' Association have been unsuccessful in resolving them suggests that they are perhaps intractable. They can be described as follows:

- Objective of the cost study — Any cost study must have a well-specified objective to provide a focus for the study. The objective might be to estimate dispensing costs per prescription for the representative pharmacy, where representative might be the mean or median-sized Ontario pharmacy. What is being purchased for the fee – whether just the dispensing function or some professional services – would have to be carefully specified.

- Front store vs. pharmacy operators — A pharmacy is typically divided into a front store that sells general

merchandise (including over-the-counter drugs) to the public and a pharmacy operation that dispenses prescription drugs. The so-called front store activities generate, according to one estimate, slightly more sales than the prescription activities [Ontario Ministry of Health 1988*b*, 22]. How should joint costs such as light, heating, rent, labour, and so on be allocated? Should they be allocated on the basis of square-foot cost, the value of sales, or profits? Furthermore, should the dispensary be allowed to subsidize the front store or vice versa?

- Price-spread — Pharmacists may receive remuneration in addition to the dispensing fee because of the price-spread. How should this be measured and treated?

- Pharmacists' roles — Pharmacists have a number of different roles: they dispense prescriptions, they supply professional services, and they are entrepreneurs. These roles may vary by store type; that is, whether they are independent stores, in hospitals, franchises, or part of a chain. How should remuneration and time allocated be assessed?

- Economies of scale — There is some evidence of scale economies in pharmacies in the United States and Australia [Cady 1975; Australia Bureau of Industry Economics 1985]. In Quebec the dispensing fee goes down once a certain level of prescription volume has been reached [Anderson 1990, 16]. This system also prevailed in Saskatchewan, where it was quite finely tuned. For example, up to 30 June 1987, the fee varied as follows:

	Fee
	(Dollars)
Pharmacy prescription volume dispensed	
0-15,000	5.49
15,001-25,000	5.23
25,000 and over	4.80

Source Saskatchewan Health Prescription Drug Plan [1988, 11].

In Ontario there is a considerable variation in store size, so costs might vary across pharmacies. Table 4-5 provides data on the store-size distribution measured between August 1985 and January 1986; a similar distribution was observed in the period October 1988 to March 1989. The range of dispensing fees in the non-ODB market shown in Table 4-4 may also reflect such variations in costs. Should such scale economies be taken into account, and if so, how?

- "Excessive" inventories — The introduction of the best available price plus a 10-per-cent mark-up in 1986 may have led to an increase in inventories because of the incentive to purchase in larger volumes direct from manufacturers or their agents rather than more frequently in smaller volumes from the wholesaler. However, since manufacturers compete on terms of payment, care must be taken in assessing the correct cost of inventories (see Chapter 5). Should inventory costs be adjusted to take this into account, and if so, how?

- Technological change — The advent of computers has significantly reduced the time taken to dispense a prescription – perhaps by as much as 50 per cent [Ontario Ministry of Health 1988*b*, 18]. How should this and other productivity enhancing factors be incorporated into fee determination? Should pharmacies that are slow to adopt such innovations receive higher fees? If yes, why?

- Rate of return — A rate of return is needed to estimate the return to assets. What is the appropriate level, particularly in view of the government's undertaking to guarantee the return? How should the assets be valued? What is the appropriate depreciation rate?

- Differences in costs — There are approximately 2,000 pharmacies in Ontario, which differ in a number of respects that affect their costs. Some, for example, employ more pharmacy assistants than others. Is the variance or range of costs among pharmacies – even in the same size class – sufficiently high that an average cost producer is of little use? If the answer is yes, is it feasible to design a survey that will reflect the dispensing costs of the largest 100 stores, which accounted for 16.7 per cent of ODB claim payments between August 1985 and January 1986, and the smallest 173 stores, which accounted for only 0.6 per cent (Table 4-5)?

A cost study could have many different objectives, each with its own problems and advantages. One possible objective is to estimate dispensing costs for the average-sized pharmacy, an approach used by the FNC chairman in his 1987 fee recommendation and followed by the OPA in its 1988 submission to the FNC. However, the vast majority of prescription volume is dispensed in pharmacies greater than the average (see Table 4-5). Given that there are scale economies, these pharmacies would receive fee revenue in excess of their costs. One solution is to select a different standard for the "representative" pharmacy, such as the median-sized pharmacy. However, this would penalize all those with costs higher than the median.[29] Another solution is to introduce a tiered structure for the dispensing fee, similar to the one in Saskatchewan. However, when the ministry suggested a limited application of this approach in 1987, the OPA rejected it [Ontario Ministry of Health 1987*a*, 17-18]. This approach would require careful measurement of breaks or discontinuities in prescription volumes

Table 4-5

Distribution of ODB claim payment among retail pharmacy stores,[1] August 1985 to January 1986

Number of stores	Amount paid to each group	Proportion of total	Cumulative amount paid	Cumulative proportion of total	Cumulative proportion of total stores
	(Dollars)	(Per cent)	(Dollars)	(Per cent)	
100	30,971,431.70	16.7	30,971,431.70	16.7	5.1
100	21,147,941.63	11.4	52,119,373.33	28.1	10.2
100	17,759,431.42	9.6	69,878,804.75	37.7	15.3
100	15,465,935.43	8.3	85,344,740.18	46.0	20.4
100	13,795,157.04	7.4	99,139,897.22	53.5	25.5
100	12,193,327.59	6.6	111,333,224.81	60.1	30.6
100	10,819,482.40	5.8	122,152,707.21	65.9	35.7
100	9,736,763.17	5.3	131,889,470.38	71.2	40.8
100	8,746,648.40	4.7	140,636,118.78	75.9	45.9
100	7,857,140.88	4.2	148,493,259.66	80.1	51.0
100	7,047,185.96	3.8	155,540,445.62	83.9	56.1
100	6,339,775.65	3.4	161,880,201.27	87.3	61.2
100	5,584,728.29	3.0	167,464,929.56	90.4	66.3
100	4,896,411.68	2.6	172,361,341.24	93.0	71.4
100	4,158,148.64	2.2	176,519,489.88	95.3	76.5
100	3,374,540.32	1.8	179,894,030.20	97.6	81.6
100	2,618,815.41	1.4	182,512,845.61	98.5	86.7
100	1,707,761.18	0.9	184,220,606.79	99.4	91.8
100	914,291.26	0.5	184,134,898.05	99.5	96.9
73	181,963.94	0.1	185,316,866.99	100.0	100.0

1 Pharmacy stores grouped in 100s and ranked by ODB claim payment volume.
Source Crosthwait Consulting Services Ltd. [1986, Exhibit 7].

by pharmacy. Quebec, for example, has selected 20,000 claims as a volume where there is a significant change in costs, while Saskatchewan used somewhat different size ranges. A survey of pharmacists' costs would have to be reliable and accurate. Nevertheless, in a large and varied market such as Ontario, there may still be considerable variation, even among pharmacists within particular size category.

One difficulty with a cost study whose only objective is to establish a dispensing fee is that it would not take into account the professional-service component of pharmacists' activities. The greater the emphasis on the dispensing fee, the more likely it is that pharmacists will hire pharmacy technicians and that the quality of service will decline. On the other hand, it has been argued that greater use of pharmacy technicians to perform routine functions will free pharmacists "to perform clinical service functions for which they are uniquely qualified" [United States Department of Health and Human Services 1990*a*, 11].

Up to this point, we have assumed that all costs can be measured and assigned between pharmacy and non-pharmacy operations. Suppose, however, as seems likely, that mistakes are made in the cost estimation. This would not only lead to hardship – too low a dispensing fee – but also distort the choices pharmacists and pharmacy owners make with respect to such considerations as location and prescription volume. For example, the dispensing fee for a certain prescription volume might be too high, thus encouraging pharmacies to grow purely because of an administrative mistake. Furthermore, once this fee has been fixed and pharmacies expand, reducing the fee would be next to impossible.

It might be useful to look at the system of supply management in the production in Canada of milk, eggs, and poultry, where a cost-of-production formula is used to set prices. It is similar to the structure of pharmacy in that there are many producers, some small, others large. The evidence is overwhelming that the system has resulted in prices that substantially exceed the costs of production and a number of other distortions [Forbes et al. 1982]. For example, one recent report found that over a five-year period Canada's chicken prices under this system were 40 per cent higher

and turkey prices 38 per cent higher than those in the United States [Advisory Council on Adjustment 1989, 116]. Supporters of the principal of regulation counter that the supply-managed boards are dominated by producers, not disinterested citizens. However, there is a strong strand in the regulation literature that argues that even when an agency is not dominated by producers, it will still reflect the interests of the regulated – they are "captured" [see, e.g., Green 1985; Stigler 1975; Ontario Economic Council 1978; and Economic Council of Canada 1979].

Determining the Import of Cost Levels

If measured costs did approximate the costs of the pharmacy dispensing a prescription, what meaning should be attached to the numbers? Costs should reflect, for a given pharmacy size, the least-cost method of dispensing its prescription volume. Furthermore, the distribution of pharmacies by size and location should reflect the least-cost method of supplying the total volume of prescriptions to Ontario's population, given its distribution and demands.

If measured actual pharmacy costs are higher than the least-cost ideal, there are two possible reasons: the income level of pharmacists and pharmacy owners is too high, and the system is inefficient – too many resources are being devoted to producing the dispensing service.[30] It is, however, difficult to determine. The usual measuring rod used by economists and public policy analysts is the level of costs that a well-functioning competitive market system yields. One cannot characterize the retail prescription drug market as such. Indeed, evidence suggests that effective competition does not exist, either in general or with respect to the dispensing fee. The Gordon commission report, for example, says that:

> In the Commission's view, and, we believe, in the view of at least some of the system participants, the fundamental structural problems of the current programmes and policies are the singular lack of effective competition throughout the retail prescription market and, in those instances when some competition exists, the barriers preventing the benefits of such competition from being passed on to consumers. In short, while some elements of the present structure promote competition, other elements hinder it. The elements which hinder it are stronger than those which promote it – thus, the overriding objective of reasonable prices for prescription drug products and services is not achieved to an acceptable level [Gordon 1984, 58-59].

On the dispensing fee in the non-ODB market, the report comments:

> The equally serious aspect of this use of the marketplace fee is the remarkable lack of competition among pharmacies. With only negligible consumer awareness that part of the price paid for prescriptions is a dispensing fee, and with strong reluctance on the part of pharmacists to provide such information, it is difficult to see how the marketplace fee represents anything other than a pharmacy's view of the fee it should receive, rather than a fee acceptable to both the providers and receivers of pharmacy professional services. The marketplace fee in no way reflects any of the competitive behaviour which is normally associated with the market mechanism [1984, 47-48].

A year later the federal Commission of Inquiry on the Pharmaceutical Industry came to essentially the same conclusion about pharmacy nationally [1985, 408-10].

While it is true that the Prescription Drug Cost Regulation Act of 1986 introduced some changes, for example, mandatory posting of dispensing fees and breaking down of the prescription prices according to the dispensing fee and the drug cost, these steps do not appear to be sufficient to bring about effective competition in the Ontario prescription drug market.[31]

An alternative method of determining whether the costs are too high or the returns excessive is to look at indicators such as the level of compensation paid to comparable pharmacists in other jurisdictions, and whether entry takes place or not. There is evidence that Ontario pharmacists' costs and returns are high. For example, the Ministry of Health found that:

- In the period 1980-87, sales in Ontario pharmacies increased much faster than did those in all Canadian retail operations.

- Over the period 1981-85, Ontario pharmacies achieved proportionally higher net profits and returns on sales, and higher owner/manager salaries than did comparable pharmacies in other provinces [Ontario Ministry of Health 1988*b*, 13].

- Judging by the rise in the number of pharmacies in Ontario by one quarter from 1979/80 to 1988/89 and the average increase in the number of ODB claims per pharmacy by 70 per cent in the same period, pharmacy is an attractive industry to enter [Ontario Ministry of Health 1988*b*, Appendix 3; and additional data supplied by the ministry].

It is difficult to argue that pharmacists and their operators should not receive remuneration sufficient to cover their costs, including a reasonable rate of return. However, there are a number of practical and conceptual difficulties with the cost-based method of determining what that remuneration should be. If costs and prices are currently higher than

they need be – and the evidence points in that direction – then using the existing cost structure to determine fees will simply validate and legitimize those inefficiencies and returns [Commission of Inquiry on the Pharmaceutical Industry 1985, 409]. As a result, it will be much harder to contain costs. As more entry takes place, and as the average pharmacy size falls, costs will rise, thus validating further fee increases.

Alternative Methods of Setting the Dispensing Fee

In order to evaluate alternatives to the current method of determining the dispensing fee, we take a two-pronged approach. First, using the concept of the dispensing fee as an appropriate model, we evaluate the following methods of setting the fee: a competitive market and auctioned franchises. (Negotiation was discussed earlier in this chapter, as was the cost-based regulatory approach.) Second, we discuss capitation, another model for compensating the pharmacist (Figure 4-2).

In considering which direction policy should go with respect to the method of determining the dispensing fee and patient/consumer copayment, several other issues have to be taken into account. The overall objective of the fee should be, as at present, to reimburse pharmacists for their services, including a reasonable rate of return on capital. The approach selected should, however, avoid the disadvantages of the cost-based system, which is not only administratively complex and cumbersome, but also economically inefficient and costly, faults more usually linked with U.S. health care [United States General Accounting Office 1991, Figure 3.1, 32]. Change necessarily involves risks, since adopting new systems can lead to unforeseen problems and difficulties. The more radical the departure from the present system, the more likely it is – other things being equal – that there will be problems. Therefore the changes should be marginal and should have some history of success and applicability to Ontario.

A Competitive Retail Market

One system that would meet many, if not all, of the criteria set out in Chapter 2, is setting the dispensing fee on the basis of a competitive market. This system would have three central elements:

- Patient/consumer copayment — All ODB recipients, except those on general welfare, family benefits, and the

Figure 4-2
Models and mechanisms for compensating pharmacists

	Setting the level of remuneration			
	Franchise via auction	Negotiation	Regulation	Competition
Compensation model: *Dispensing fee* Pharmacists receive a fixed fee for each prescription dispensed to cover the costs of their professional services. *Capitation* Pharmacists receive a fixed dollar amount for each recipient for all their prescriptions over a given time period.	• Pharmacists are asked to bid to supply the needs of patients in a given geographic area. • Government, perhaps with pharmacy, sets the parameters; e.g., size of geographic area, length of contract.	• Pharmacists and health officials meet to determine an acceptable level of compensation. • Various sorts of data could be brought to bear on such negotiations, including cost data, comparable professional pay levels, overall government policy. • Various negotiation mechanisms might be introduced, such as Ontario's elaborate system in which there is an arbitrator.	• A regulatory body takes submissions and recommends an appropriate level of remuneration. • The regulatory body might consist of industry experts, disinterested citizens, and/or producers. • The criteria usually employed by regulatory boards to determine levels of remuneration are cost-based formulas.	• Pharmacists set their own individual levels of compensation. • Competitive marketplace created by charging consumers a copayment and compelling pharmacists to disclose fees, professional services, and compensation. • Market might be policed by competition law officials.

Guaranteed Annual Income System for Ontario senior citizens (GAINS), would pay a fixed percentage of the dispensing fee for prescription drugs directly to the pharmacist. The pharmacist would then collect the remainder from the ODB. However, the ODB would pay the excess over, say, $100 per recipient in any calendar year. In British Columbia, senior citizens pay 75 per cent of the fee on all prescriptions. However, once the maximum has been reached in any calendar year, the drug program refunds the difference on a monthly basis for amounts in excess of $20.

- Fee setting — Each pharmacist would set either a single dispensing fee or a schedule of fees to cover different professional services in addition to the basic dispensing function. This fee would cover courses of treatment of up to a maximum of 100 days. It would be communicated to the public through the media, together with professional services the pharmacist offers such as patient counselling and educational literature.

- Marketplace referee — The ODB would monitor the fees set by the pharmacist and have a financial stake in the success of the scheme. The fee (or schedule of fees) would have to be registered with the ODB (or the College of Pharmacists as at present). In the initial phases, a limit could be placed on the fee; for example, that it not exceed 15 or 25 per cent of the weighted mean. Each pharmacy fee would be weighted by the proportion of total prescriptions (or claims) it accounted for. This average fee would *not* be made public.

The proposed copayment should encourage the dispense-as-written policy, as it did in British Columbia where there was a marked increase in quantity dispensed per prescription when copayment was introduced among seniors. One of the problems with this is, of course, that too large quantities may be dispensed and expensive medication wasted. However, a trial scheme (not limited to seniors) was carried out at four pharmacies in British Columbia, and the results suggest that this may not be a serious problem. Under the scheme, which only applied to drugs known to have a high incidence of side effects and/or low tolerance, the patient/consumer received a trial two-week supply. B.C. Pharmacare paid the fee and drug cost. If the drug worked satisfactorily, the patient/consumer received the balance of the original prescription, paid 75 per cent of the fee, and B.C. Pharmacare paid the remaining 25 per cent plus the drug cost. According to B.C. Pharmacare, the savings in unused drugs did not offset the extra fee expenditure so the scheme will probably not be extended to all of British Columbia.[32]

The contribution by ODB recipients should be based on a fixed *percentage* of the fee and not a fixed *dollar* amount. When it is a fixed amount there is no incentive for ODB recipients to search for lower-cost pharmacists, since the amount paid (whether $3 or nothing) will be the same irrespective of the pharmacy selected. In addition, when the copayment is a percentage rather than a maximum, the total fee is constrained, thus eliminating the need for complex fee negotiation procedures.

One of the criteria with which to evaluate changes in the system is their total effect on public and private drug expenditure. A fixed dollar copayment could increase total expenditure on dispensing fees, but decrease governmental expenditure. At present the Ministry of Health pays 100 per cent of the fee. This provides a considerable incentive for the ministry to bargain very hard to get a lower fee. If a portion were paid by the public, there would be less incentive on the part of government to bargain to obtain the lowest possible overall fee.[33] Its incentive would rather be to obtain the lowest possible government contribution. Thus it might make a trade-off between a higher overall fee with a higher patient copayment contribution and paying less itself.

The proportion of the copayment would have to be high enough to provide an incentive for the ODB recipient to search for a pharmacy offering the services required at the best price. In British Columbia it is 75 per cent, and in Newfoundland seniors covered by the provincial government drug plan pay all of the fee. Since seniors typically have the time to engage in search and are heavy users of drugs, a much lower dispensing fee copayment may be all that is required.

The purpose of the copayment is to create a competitive market in which the dispensing fee reflects costs, not to penalize ODB recipients and jeopardize access. However, as noted in Chapter 3, the ODB is currently excessively generous in meeting those aims. It should be possible to introduce a competitive market with a copayment and exempt the poorest groups. Even for those who are not exempted, there could be a ceiling above which the government would pay 100 per cent. (It could, of course, be graduated so that for expenditure between, say, $100 and $200 the government pays 70 per cent, and above $200, 100 per cent.) This would protect people from very high or catastrophic drug costs.

Fee Disclosure

There is little or no economic justification for the present regulations against disclosing dispensing fees and professional services. A series of reports on professional

regulation in Canada in the late 1970s and early 1980s argued that such regulation does little to protect consumer quality [Muzondo and Pazderka 1980; in Ontario, Trebilcock et al. 1979 and Leal et al. 1980; in Quebec, Office des Professions du Québec 1977]. Furthermore, studies of jurisdictions in the United States that did allow advertising of some medical services and those that did not demonstrated no difference in quality between them, but there were price differences [Cady 1975 and 1976 on pharmacy; Bond et al. 1980 on optometry]. Indeed, communicating to the public the range of professional services offered could lead to greater product differentiation and reward pharmacists who provide good service.

Evans and Williamson put the case for disclosure of fees and the use of the market quite forcefully:

> The marketplace cannot be relied upon to weed out the snake oil salesman because of, inter alia, the technical difficulty of establishing cause and effect in the relation of drugs to health care. But the same logic does not justify interfering with a consumer's decision to use a pharmacy with or without, e.g., delivery services. And if it does not, then it cannot justify preventing pharmacies from adjusting their relative prices to reflect their different service packages, and making these price differentials known to consumers. Only in this way can consumers indicate whether they consider the extra services worth their extra costs [1978, 64-65].

There is also a legal case against barring the disclosure of dispensing fees and professional services. In a recent decision of the Supreme Court of Canada, various restrictions on the advertising of dental services imposed by the Royal College of Dental Surgeons of Ontario were struck down.[34] What makes this case particularly relevant is that these restrictions were imposed pursuant to the Health Disciplines Act – the same legislation that provides statutory authority for regulating pharmacy in Ontario. Furthermore, while the restrictions on the dental profession that were struck down were not concerned specifically with price disclosure, the grounds that the court used to decide that the restrictions were unwarranted were that in areas where consumers could be expected to make sensible, rational choices, denying them information on which to base those decisions is not justified. It is possible, therefore, that if the issue of restrictions on dispensing fee disclosure were considered by the court, it might well strike them down.

Professional Services: Regulation or Competitive Markets

One of the characteristics of inquiries into health care in Canada during the past 20 to 30 years is the belief that there is a need or demand for the professional services of the pharmacist at the retail level and that their provision should be mandated by law operating through a professional regulatory body. In large part, this reflects the need to redirect the talents of pharmacists, since their compounding function has been assumed by drug manufacturers.[35] Yet successive inquiries report that pharmacists are mainly perceived as providing a dispensing rather than professional service, despite increased educational qualifications and other "improvements" mandated by regulation.

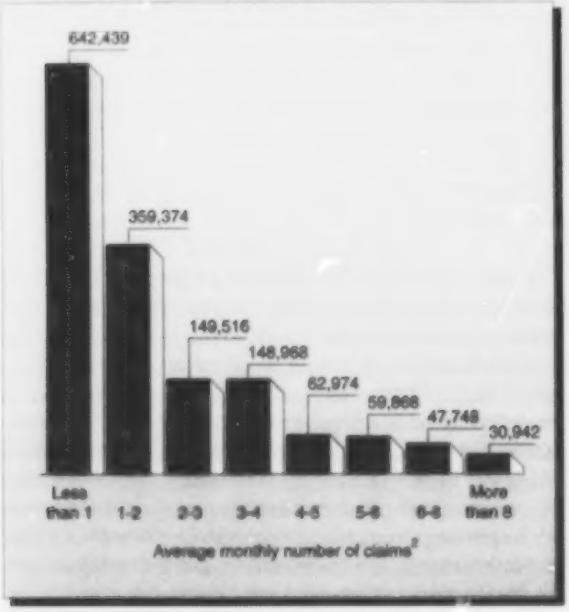
The Pharmaceutical Inquiry of Ontario falls squarely into the tradition of these past inquiries [1989*b*, 1989*c*, 1990*a*]. For example, it states that mandated services should include "an appropriate consultation area where patients can discuss their medication with a pharmacist, in privacy and relative comfort," and "a professional products area, adjacent to or contiguous with the dispensary, where all non-prescription drugs . . . must be located" [1990*a*, 126]. These are likely to result in an increase in costs and benefits, neither of which are quantified by the inquiry. However, since about one third of pharmacies in Ontario report that they already have a consultation area, these costs and benefits could be estimated [Cockerill and Williams 1989, 10].

One implicit assumption of the regulatory approach of the Pharmaceutical Inquiry of Ontario is that all patient/consumers have the same requirements, possess the same knowledge, and require the same level of service [1989*c*, 9-10, 1990*a*, 125-27]. This is manifestly not the case. Some consult their physician; others refer to the numerous books on drugs (including that issued by the Canadian Medical Association [1990]). Some people are on long-term therapy and may require careful monitoring; others take the odd antibiotic and do not need to be monitored. Figure 4-3 shows that 42 per cent of ODB patient/consumers consume less than one drug per month, two thirds two or less, while 9 per cent consume five or more per month. In view of this variety, it would not be appropriate to mandate uniform service levels. This does not mean, of course, that the Ontario College of Pharmacists ought not to develop guidelines for new services and pharmacy layout, but it should leave it to the discretion of individual pharmacies to decide whether or not to offer the service.

Another implicit assumption of this "regulatory" approach is that the patient/consumer is unable to evaluate the services offered by pharmacists. Once again, this is manifestly not the case for a variety of services offered by pharmacists. There may be some professional services that yield substantial returns compared to the costs, but that patient/consumers are unable to evaluate or are unprepared to pay for, such as patient monitoring and discussions with

Figure 4-3

Average monthly number of claims by number of persons, Ontario Drug Benefit, 1988/89[1]



1 For the financial year ending 31 March 1989.
2 The actual total annual claims, which were used to derive the monthly claims, were, reading across the figure: 1-10; 11-25; 26-35; 36-50; 51-60; 61-75; 75-100; 100 and over.

SOURCE: Based on information supplied by the Ontario Drug Benefit, Ministry of Health.

physicians. It is not clear, however, that these should be mandated through regulation. In many cases they are quite specific to particular groups of patients, and broad regulations are therefore inappropriate. U.S. studies on the impact of services that are mandatory, such as patient counselling, suggest that such regulations have had little effect on either the amount or quality of counselling provided [United States Department of Health and Human Services 1990*a*, 9].

An alternative approach is for the ODB – perhaps in partnership with private insurers – to negotiate with pharmacists for the provision of these services with, of course, appropriate payment.[36] Certainly it would appear that pharmacies in Ontario are in favour of greater professional-service activities [Cockerill and Williams 1989, 19]. Monitoring people on multiple medications might be a useful starting point, since they often need advice and guidance with respect to drug therapy (see Figure 4-3 for an indication of the size of this group). Assuming that they make six claims per month (based on a study cited by Hepler and Strand [1990, 538]), the group consists of about 80,000 persons.[37] Before negotiations could start, however, it would be necessary to examine ODB records for a sample of this group so that any potential problems could be carefully specified beforehand. One might find, for example, that only a subset of the 80,000 require careful monitoring or a more direct approach from the ODB if there are some simple common problems.

Quebec has already taken some steps in this direction. Since 1976 that province's drug plan has paid pharmacists for not filling a prescription if it is not in the patient's best interest and for suggesting in writing to physicians either to stop or change a prescribed medication. For these services pharmacists are paid an amount equal to the fee and double the fee, respectively. However, neither of these services has been provided extensively. In 1989 they constituted less than 0.005 per cent of all claims paid by the Quebec plan for those 65 years and older [Quebec Régie de l'Assurance-maladie du Québec 1990, tableau D, 205, and tableau G, 207]. Negotiations are currently in progress, however, not only to remove the disincentives for providing such services, but also to extend the scope of the "opinion pharmaceutique."[38]

The disclosure of professional services, combined with contracts between pharmacies and the ODB and/or private drug plans for specific professional services, would ensure that the professional expertise of pharmacists is used sensibly and efficiently. These measures would remove the information barriers that discourage the use of such services,[39] identify the appropriate agent – be it consumer or third-party payer – who uses the services, and take into account the incentives under which pharmacists operate. It is only by recognizing such factors that the appropriate mix of professional services is likely to be supplied; simply mandating the provision of professional services has little chance of success [Maule 1990].

Efficient Use of Pharmacy Resources

It has been estimated that prescription prices would fall by between 11.4 and 16.7 per cent if pharmacists' and their assistants' time were more rationally allocated [Evans and Williamson 1978, 106]. A competitively set dispensing fee has the potential to do this. At present, highly trained pharmacists conduct dispensing tasks that could be just as efficiently carried out by pharmacy assistants.

There are currently no regulatory limits on the number of pharmacy assistants that can be supervised by a pharmacist, although it appears to be a subject of constant interest to the Ontario College of Pharmacists, who has issued

guidelines on the role of the pharmacy assistant. There is evidence for the United States that restrictions on the number of assistants a dentist can supervise and the functions that they perform raised the average price of a dental visit by 11 per cent in 1970 and 7 per cent in 1982 [Liang and Ogur 1987, 2]. Since dental assistants perform many traditional and some expanded functions as well as dentists do, greater use of assistants as a result of relaxing restrictions is unlikely to lead to reduced quality of care.

In those instances where the patient/consumer only requires the dispensing function, the ratio of pharmacy assistants to pharmacists will be high and the main function of the pharmacist will be supervising and instructing. There is room for expansion in this service, since on average there appear to be as many pharmacists as pharmacy assistants in Ontario [Cockerill and Williams 1989, 9-10, and Table 3-5, 16]. However, where the professional-service component is more important – perhaps for older people on multiple medications – then the pharmacist's clinical-service functions will be more important.[40]

A competitive market also has the potential to lead to a better allocation of pharmacy resources as nonpharmacy operations become less important. To the extent that larger pharmacies, particularly those belonging to food chains such as Loblaws and Steinberg, are able to grow in a more competitive environment, pharmacists in corner stores may close and become full time rather than part time.[41] Thus the perceived shortage of pharmacists would be alleviated due to better allocation of pharmacists' time [Canada Royal Commission on Health Services 1965, 30-33; Ontario Committee on the Healing Arts 1970, vol. 2, 222-24]. Furthermore, evidence from the United States, including case studies, suggests that one form of retail outlet (including mail order) is not any more conducive to the provision of professional services than another [United States Department of Health and Human Services 1990*a*, 9, 16].

Keeping the System Honest

Markets sometimes do not work well, even when there are many small producers, each with little power to affect price. For example, industry associations might collude to set prices, conditions of sale, and so on. The government of Ontario, with its responsibility for paying a portion of the dispensing fee, would have an incentive to monitor the activities of pharmacists to ensure that there is no price-fixing. If price-fixing were suspected, the Federal Bureau of Competition Policy at Consumer and Corporate Affairs – who has over the years prosecuted pharmacy associations for various price-fixing offences in restraint of trade in British Columbia, Nova Scotia, Ontario, and Quebec – could be brought in.[42] The initial upper limit placed on the fee would prevent local pharmacy monopolies from exploiting their positions unduly and allow some range in the service/price combination. Some might be concerned that competition might become cutthroat, but this is unlikely as the current lowest usual and customary fee is already 60 per cent lower than the median fee (Table 4-4).

A Competitive Market-Based System: B.C. Pharmacare

British Columbia's Pharmacare program is a working model of the sort of competitive market-based system proposed here. British Columbia is, in fact, the only province in Canada to have a fee set by the marketplace. All the others have systems similar to Ontario's.[43] British Columbia moved away from a negotiated dispensing fee in 1977 because of the kinds of difficulties Ontario is experiencing [Australia Bureau of Industry Economics 1985, 44]. Under Pharmacare, each pharmacy sets its own usual and customary dispensing fee within an upper limit, although there are restrictions on the disclosure of fees and professional services as there are in Ontario.

There have, however, been some problems. In particular, there was concern in the mid-1980s that average quantities dispensed were too low – even though up to 100 days' worth of drugs could be dispensed for one fee – and that the marketplace was not competitive enough. To address these problems, the province introduced a copayment scheme similar to the one outlined earlier. The impact seems to have been to increase average quantity dispensed (Table 4-3) as well as to hold the dispensing fee at around $6. Furthermore, it does not appear to have led to reduced consumption of drugs [Marcantonio 1989, 1].

Other Copayment Mechanisms

Attention has been confined to copayment mechanisms that are related to the dispensing fee.[44] As noted earlier, in some provinces the copayment is a proportion of the total price of the prescription, including both the dispensing fee and the drug cost. In the 1980s in the United States, several state Medicaid programs introduced a drug cap whereby they paid for a certain number of prescriptions per month, and beyond that the patient/consumer paid 100 per cent of the prescription.

The goal of these copayment mechanisms is somewhat similar to those that are linked to the dispensing fee. The

most obvious common goal is to reduce public funding of drug programs; another is to raise people's awareness of drug and dispensing costs. However, beyond that, it is the differences that stand out. In Saskatchewan, copayment on the total prescription cost was introduced to encourage physicians to prescribe less expensive interchangeable brands. Another objective was perhaps to encourage the substitution of cheaper, older drugs for more expensive, newer drugs, where both old and new are equally effective. The motivation for the drug cap is not so clear, unless perhaps it was an attempt to reduce overprescribing. (These three issues – interchangeability, old vs. new drugs, and overprescribing – are discussed in Chapter 7.)

One study of the impact of a drug cap in comparison with a fixed dollar copayment per prescription demonstrates how careful attention needs to be paid to the design and impact of copayment schemes. In September 1981, New Hampshire Medicaid introduced a drug cap, where the plan paid for three prescriptions per month. Eleven months later this was replaced by a copayment of $1 per prescription. Soumerai et al. [1987] analysed the impact of these changes. Both schemes resulted in similar savings for Medicaid, but the drug cap led to a marked drop in the number of prescriptions among recipients of multiple drugs – predominantly females and the elderly or disabled. The decline occurred for both "ineffective" and "essential" medications. For recipients of multiple drugs the average number of prescriptions dropped from 5.2 to 2.8 per month. In comparison, the $1 copayment resulted in an increase in prescriptions to near their levels before the introduction of the cap, with much less effect on multiple users. In subsequent work it was shown that many of those multiple drug users were admitted to hospital while the drug cap was in effect. Thus two copayment schemes with direct savings of the same magnitude had quite different impacts on the health system and patient welfare.

Auctioned Franchises

A system where the patient is responsible for seeking low-cost pharmacies and where pharmacists have the means and the incentive to communicate their fees to the consumer is one way of establishing a competitive market. Another is for the government to auction the right to supply ODB patients in a particular area. The organization of such a system would be as follows:

- The province would be divided into geographic areas, each of which would be supplied by one pharmacy. The size of the area would depend upon such factors as the population density, the size and number of existing pharmacies, the percentage of the population who are ODB recipients, and available scale economies.

- Every six months (or whatever period is deemed appropriate), a competition would be held for the right to supply the geographic area with ODB prescription services. The winner would be the qualified bidder with the lowest dispensing fee.

This auction system has many of the same characteristics as the competitive market copayment scheme. There are a number of important differences, however. The auction system is likely to be more administratively complex than the competitive market system. Defining the geographic areas is likely to be a very difficult task and complex trade-offs would have to be made. Generally, the larger the geographic area, other things being equal, the greater the pharmacy that will serve the area. With such economies, the fee would be lower than if the area were subdivided into a series of smaller areas. However, the larger the area, the greater the distance that a recipient would have to travel, which would effectively raise the price to the consumer. With a competitive market-based system, consumers could make their own choice as to the appropriate trade-off between distance travelled, quality of service, and fee. Since preferences are likely to differ, a uniform auction system may decrease welfare. Furthermore, there are likely to be recontracting problems. Pharmacists rely to a considerable degree on ODB business. In an auction system, pharmacies that lose could experience considerable difficulty and even go bankrupt. This could lead to the domination of each area by one large pharmacy and result in monopoly problems.

Capitation

Another approach to establishing the level of pharmacists' compensation is capitation [Chiles 1988]. Under capitation the pharmacist receives a fixed payment per patient, irrespective of the number of drugs dispensed. There might be different capitation levels depending upon the plan type within the ODB, reflecting different utilization rates. The rate could be monthly or annual; the shorter period gives the patient/consumer an opportunity to switch pharmacies. Capitation is practised for service to nursing homes in British Columbia and Manitoba, and on a more restricted basis in Nova Scotia [Canadian Pharmaceutical Association 1989].

The capitation rate could be set in a competitive marketplace, under an auction system, or through negotiation or regulation. The merits and faults of these systems as ways

of determining the dispensing fee also apply to capitation. The advantage of the capitation system is that under it pharmacists are motivated less by commercial concerns and more by health-care concerns, since for a given capitation rate income will be unrelated to the quantity of drugs dispensed. However, pharmacies could attempt to enhance their income by screening out heavy users of drugs. Furthermore, to the extent that capitation rates are linked to overall utilization, pharmacists have an interest in keeping the rates up.

It could be argued that in a properly functioning market where prices and professional services are disclosed, consumers will select pharmacies which offer good service and counselling. Nevertheless, given the extent of the change that capitation would involve and the fact that its benefits are by no means certain, it is probably inappropriate at the present time. Given its touted advantages, however, some pilot projects in a community setting might be useful.

Impact

The solutions to the problems and difficulties of setting dispensing fees in Ontario have not been resolved by the 1986 Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act. Indeed, because the system is now enshrined in legislation, change may be more difficult. In this chapter we argue that the appropriate mechanism with which to set the dispensing fee is a patient/consumer copayment combined with fee disclosure by pharmacists and monitoring by government. This has the potential to meet all of the objectives of the 1986 legislation as well as lead to better allocation of pharmacy resources – a particularly important issue given the anticipated rise in demand for drugs with the aging of the population and the rise in drug consumption across all age groups.

What would be the impact of the scenarios outlined above on the costs of the ODB? In Table 4-6 we present estimates

Table 4-6

Estimated impact of various fee-setting mechanisms on ODB expenditure, 1988/89

	Fee level assumed	
	Actual ODB fee: $6.22	Representative private-sector fee: $8.00[1]
Total ODB fee expenditure	100	128.6
	(No copayment, status quo)	
Dispense-as-written policy successfully implemented[2]	80	102.9
	(Copayment on fee, competitive marketplace)	
Dispense-as-written policy successfully implemented[3]	70	90.0
Patient copayment of 75 per cent plus successful dispense-as-written policy	17.5	22.5
Patient copayment of 75 per cent, no copayment after a ceiling of $125, plus successful dispense-as-written policy[4]	27.03	44.61
Patient copayment of 75 per cent, no copayment after a ceiling of $125, successful dispense-as-written policy, no copayment for those receiving GAINS, family benefits, and general welfare[5]	46.49	60.70

1 Derived from Table 4-4.
2 Uses data in Table 4-3 for 1986 and 1987 and discussion in text which estimates a 20-per-cent drop in claims.
3 Uses same approach as in note 2, except data is for 1988 and 1989.
4 The deductible for $6.22 translates into 20 claims and the $8 fee into 21 claims for which a copayment must be made. The data in Figure 4-3 were then used to estimate the number of claims for which a copayment was paid by the beneficiary. In each size category it was assumed conservatively that all claimants were at the bottom.
5 Unpublished Ministry of Health data suggest that for 1988/89 costs for general welfare and family benefits recipients were on average 48.18 per cent of the mean cost for all those eligible under the ODB; those funded by the Ministry of Health were 33.52 per cent above the average. We assumed that the same relationship held for claims. The number of family benefit and general welfare recipients is given in Table 2-2; according to the Ontario Ministry of Revenue, the average monthly number of GAINS recipients was 161,000 in 1988/89. Since people usually stay on GAINS a year, we used their figure.

of total ODB fee expenditure under the various schemes. All the estimates are indexed relative to actual ODB expenditure on fees in 1988/89. A market-set fee of $8 was chosen. This is probably an upper limit, since British Columbia's average dispensing fee was $5.94 in February 1989, and $6.08 in August 1990 [Anderson 1989, 11; 1990, 14], and its copayment and maximum patient/consumer contribution were similar to those in Table 4-6. The estimates, although rough, indicate what might be expected under somewhat restrictive assumptions.[45]

We have taken an increase in the average quantity dispensed per fee to be the main patient/consumer reaction to the introduction of the copayment. In other words, we have assumed that the copayment affects only fee and not drug expenditure. This approach was adopted for three reasons: first, under the ODB an upper limit of one month was placed on the length of course of treatment that could be dispensed at a single time; second, those aged 65 and over – the most important eligible group under the ODB – are large consumers of maintenance drugs, many of which can be dispensed quite safely for more than a month at a time; and, third, evidence from British Columbia, both before and after the introduction of the copayment on the fee, shows that larger quantities would be dispensed in a copayment scheme.

An alternative approach is to assume that the impact of the copayment is to reduce demand for prescriptions, with no impact on average quantity dispensed; that is, that ODB expenditure are reduced because of fewer fees and drugs. This is the approach taken by Hurley [1989] in evaluating the financial impact of various copayment schemes on the ODB.[46] Depending on the assumptions made about the responsiveness of patient/consumers to the copayment, it is estimated that with a 75-per-cent fee copayment and a $100 maximum annual payment per patient/consumer, ODB expenditure would be reduced between one quarter and one half. If the copayment were to drop to 25 per cent, the reduction in expenditure would be between one tenth and one fifth [Hurley 1989, Table 13, 113-15].

Whether a copayment leads either to an increase in quantity dispensed per claim, a decline in the demand for drugs, or some combination thereof,[47] major reductions in ODB expenditure are certainly possible. Furthermore, if the copayment were a percentage of the fee, the retail market would provide a more appropriate bundle of professional and dispensing services, and in a competitive marketplace pharmacists would be rewarded for the services they provide. The implementation would, of course, have to be carefully monitored.[48]

5 Drug Reimbursement Systems: Best Available Price, Actual Acquisition Cost, and Standing Offer Contracts

The government of Ontario accounts for a significant part of the province's drug market – some estimates put it as high as 50 per cent. It has set up its own system to determine drug prices and reimburse pharmacies for dispensing drugs. An important motivation for this intervention on the part of the government is to minimize expenditure on drugs prescribed by physicians and dispensed by pharmacists. It has introduced rules that, combined with interchangeability, encourage the dispensing of lower-cost brands, while according to other rules, drugs offering little price or therapeutic advantage over existing products are not eligible benefits under the ODB.

In this chapter we describe the system of determining drug prices, pharmacy reimbursement, and price and product selection rules that was introduced with the 1986 legislation. We then examine how successful the 1986 legislation was in removing the "spread" – the difference between the ODB-determined reimbursement price and the price the pharmacist pays to the drug firm or wholesaler (see Chapter 3). Finally, we consider alternatives to the current system, ranging from minor adjustments to fundamental change based on models from other jurisdictions. These are: actual acquisition cost (AAC), a system adopted in British Columbia and for a time in New Brunswick and Nova Scotia, and advocated by the Pharmaceutical Manufacturers Association of Canada; bidding or tendering, used in Saskatchewan; and, finally, a system of mandating prices advocated by the Pharmaceutical Inquiry of Ontario [1990*a*].

The ODB Reimbursement System

For each drug product that is an eligible benefit under the ODB, a price – the best available price or BAP – is set for reimbursement purposes, and a 10-per-cent mark-up is added to this. The actual reimbursement price paid by the ODB depends on the price and product selection rules, and whether the drug is classified as single source, interchangeable, or noninterchangeable.

Best Available Price

The definition of the BAP is set out in Section 18 (4) of the Ontario Drug Benefit Act as follows:

> The lowest amount, calculated per gram, milliliter, tablet, capsule or other appropriate unit, for which a listed drug product of that drug in that dosage form and strength can be purchased in Canada for wholesale or retail sale in Ontario and in calculating that amount, the Lieutenant Governor in Council shall deduct the value of any price reduction granted by the manufacturer or wholesaler or their representatives in the form of rebates, discounts, refunds, free goods or any other benefits of a like nature.

Essentially the same definition appears in the Prescription Drug Cost Regulation Act (1986, Section 7 (1)).

The BAP is not necessarily a list or catalogue price but is meant to be as close as possible to the actual transaction cost, net of special deals and discounts. Because of the problems of the late 1970s and early 1980s (described in Chapter 3), the definition of the BAP does not specify package size. Furthermore, the BAP is the lowest price to the wholesaler, or to the retailer who purchases direct from the manufacturer or through an agent. The legislation specifically excludes account being taken of drug prices for hospitals in setting the BAP (Ontario Drug Benefit Act of 1986, Section 18 (3)).

The BAP is determined by officials in the Ministry of Health from several sources of information, including previous formulary prices, ODB purchases of the drug, and, most important, information submitted by manufacturers,[1] who are asked by the ministry to submit information about the BAP for various package sizes. Those who fail to do so before the deadlines are barred from increasing their prices.

The BAP is based on the package size that is accessible to the majority of pharmacists. Larger pharmacists are therefore able to purchase larger package-sizes and realize lower prices. However, the discounts realized from buying in larger package-sizes do not appear to be that great, at only 3 to 5 per cent more than those realized for the package size selected for the BAP. Where competition is legally allowed to occur is in discounts for prompt payment and delaying payment for up to 120 days.[2]

The legislation empowers inspectors appointed by the Minister of Health to seize records and other materials from physicians, pharmacists, wholesalers, and manufacturers to determine whether they have complied with the legislation.

Knowingly furnishing false or incomplete information carries the penalty of a fine (Ontario Drug Benefit Act, Section 15), manufacturers having their drug products delisted or not designated as an eligible benefit (Section 16 (2)), or having a new BAP set by the ministry.

In 1989/90, after receiving reports of listed drug products being sold at prices below the BAP listed in the formulary, the Ministry of Health carried out a small number of inspections.[3] As a result of the documentation uncovered, the BAPs in the February 1991 formulary for 10 drug products were set at a lower level than they would have been had they been based on data submitted by the firms concerned. Pharmacy claims for these 10 products for the period 1 July 1990 to 14 February 1991 were reassessed on the basis of these lower BAPs.[4] Estimated recoveries were $1.2 million [Archer 1991, 114].

When there is a sudden jump in prices that bears no apparent relationship to inflation, or a new product appears with a high entry price, the Ministry of Health may negotiate a lower price. For example, if manufacturers decide to switch from selling wholesale only to selling through a distribution agent, they may request that the BAP be raised to include the distribution charge. However, after three or four manufacturers did this in 1986/87, the ministry refused to approve any more such agreements.

The legislation gives the Minister of Health some discretion in setting the BAP in addition to any moral suasion the ministry may exercise. Indeed, since 1 January 1988 the ministry has generally used increases in the consumer price index (CPI) to determine whether or not a price increase is excessive, although no regulations have been passed as such. This partly reflects a switch to different distribution systems, but it also reflects the fact that a number of manufacturers have requested large price increases [Ontario Ministry of Health 1988*b*, 6-7]. In October 1991, 42 drug products were delisted from the formulary because their proposed price increases were too high (letter to Ontario pharmacists from the director of the ODB, 10 November 1991).

Mark-Up

The drug cost that appears on the prescription is the BAP plus a fixed percentage mark-up.[5] Under the Ontario Drug Benefit Act this percentage shall be not less than 10 per cent nor greater than 20 per cent (Section 18 (2)). A similar provision appears in the Prescription Drug Cost Regulation Act (Section 7 (3)(b)). The Lieutenant Governor in Council has set the mark-up at 10 per cent. How the percentage should be determined or its purpose are not specified in the legislation. It appears to be for wholesaling and to ensure that small pharmacies are not disadvantaged if they cannot buy at the BAP.

Price and Product Selection Rules

There are three categories of drugs for which different pricing and product selection rules apply. These are as follows (see also Table 5-1):

- Interchangeable drugs – Whether the brand or the drug name is specified on the prescription, the pharmacist is reimbursed no more than the BAP of the lowest-priced interchangeable product plus 10 per cent. For example, no matter which brand of diazepam 5-mg tablets is dispensed, the pharmacist will only be reimbursed $0.0050 plus 10 per cent. The only exception is when physicians specify a particular brand, write in their own handwriting "no substitution" on the prescription, and complete a special ODB form. However, in such instances, pharmacists only receive the BAP and not the fixed 10-per-cent mark-up.

- Noninterchangeable drugs – These are drugs of which more than one brand is available and listed in the formulary. Pharmacists must dispense the brand specified by the physician at that brand's BAP plus 10 per cent. For example, if the physician prescribes Grisovin, it must be dispensed at $0.1521 per tablet, despite the fact a lower-priced brand of the drug is available. It is not clear what rule should be followed in those instances where a prescription is for the drug name rather than the brand name. Presumably the pharmacist exercises some discretion in selecting the brand or contacts the physician for clarification. Frequently, noninterchangeable drugs are classified with single-source drugs.

- Single-source drugs – Pharmacists must dispense the brand specified at the BAP plus 10 per cent. Since there is only one brand, the pharmacist has no choice but to dispense the brand in the formulary. For example, a mebendazole tablet would cost $2.4383. Pharmacists are *not* permitted to choose another drug or another brand (assuming one existed, but was not listed in the formulary).[6]

Pharmacy Reimbursement

The pharmacist is responsible for billing the ODB and purchasing the drug in the marketplace, either directly from the manufacturer, a route favoured by suppliers of interchangeable products, or indirectly, wholesale. The ODB does not supply drugs or control the price paid by the pharmacist beyond setting the BAP.

Table 5-1

An example of pricing and other information on interchangeable, noninterchangeable, and single-source drugs in the Ontario formulary, 1989

Drug name	Drug identification number	Brand name	Manufacturer	Best available price
				(Dollars)
Interchangeable				
diazepam 5-mg tablet	013285	Valium	Hoffman-LaRoche	0.0050
	013765	Vivol	Frank W. Horner	
	272442	Novodipam	Novopharm	
	280429	E-Pam	ICN Canada	
	362158	Apo-Diazepam	Apotex	
	396230	Diazepam	Drug Trading Company	
Noninterchangeable				
griseofulvin 125-mg tablet	012246	Grisovin FP	Glaxo Canada	0.1383
	028766	Fulvincin U/F	Schering	0.1304
Single source				
mebendazole 100-mg tablet	556734	Vermox	Janssen Pharmaceutica	2.4142

Source: Ontario Ministry of Health [1989a, 3, 62].

Individual pharmacists bill the ODB for each claim. An individual claim record submitted to the ODB includes the date of dispensing the claim, the patient/consumer's ODB number and Ontario health card number, the product's drug identification number (DIN), the quantity claimed, the total dollar amount, and the prescription number. In the future, pharmacists will probably also be required to submit the physician identification code and the length of the course of treatment supplied. Approximately 60 per cent of the claims are submitted electronically.

Each DIN has a corresponding BAP which, added to the 10-per-cent margin and multiplied by the quantity dispensed, is the amount paid by the ODB. This is then deducted from the total amount of the claim. The balance is the dispensing fee. If this is greater than the negotiated fee, the claim is adjusted downward. If it is less than the negotiated fee, then no adjustment is made. The fee, like the BAP, is a maximum.

In submitting their claims, pharmacists do not forward the actual prescription receipts. In order to ensure that there is no fraud involved in the processing of claims, the ODB checks the claims made against actual prescriptions dispensed by visiting individual pharmacies and inspecting their records. In a very small number of cases prosecutions are launched.

Archer [1991] evaluated the ODB claims payment controls and concluded they are operating satisfactorily. In contrast, the postpayment inspection process was deemed less than satisfactory. Recommendations for improvement were made and accepted by the ODB. In addition, Archer discovered serious billing irregularities by pharmacies, which were referred to the provincial police.

Eliminating the Spread: Has the BAP Been Successful?

To determine whether the BAP has eliminated the spread, we compared prices before and after its introduction. Unfortunately, there are no reliable data on the size of the price-spread prior to the implementation of the BAP. The ministry claims that it was $30 million [Ontario Ministry of Health 1988*c*, 12]. We used Saskatchewan prices as a benchmark for actual transaction prices, as the Ontario provincial auditor did in the early 1980s [Archer 1984]. Finally, we examined the results of the Ministry of Health inspections in 1989/90 to quantify the spread.

The Impact of the BAP on ODB Drug Prices

We analysed two samples, consisting of the 10 interchangeable and the 10 single-source drugs that had the highest

volume of sales in their respective categories in March 1986 (Table 5-2). In that month these 20 drugs accounted for 25.2 per cent of the money paid by the ODB; single-source drugs accounted for 15.7 per cent and interchangeable drugs for 9.5 per cent.

These samples were selected for several reasons. Eliminating the size of the spread on high-volume drugs has the potential to yield the highest savings for the ODB. Interchangeable drugs were selected because the concern in the late 1970s and 1980s over the price-spread focused on them. Single-source drugs provide something of a control group. Furthermore, manufacturers of single-source drugs have a monopoly on their sale, so the majority of the demand for these drugs is generated through advertising to the physician, rather than cutting the price to the pharmacist or wholesaler. Thus prices of single-source drugs are unlikely to fall because of the BAP. Finally, prices are examined over several years in order to assess the long-run and short-run influence of the BAP. In the past, while the spread was eliminated in the short run, it subsequently re-emerged (see Chapter 3).

Table 5-2

Short-run and long-run impact of the BAP on the 10 highest-dollar-volume[1] single-source and interchangeable drugs under the Ontario Drug Benefit, 1986, 1987, and 1989

	Price[2]		
	Before BAP, 1986	After BAP	
		1987	1989
	(Dollars)		
Drug, strength, and dosage form			
Single source in 1986[3]			
ranitidine HCl 150-mg tablet	0.8232	0.9585	1.0308
nifedipine 10-mg capsule	0.3830	0.4236	0.5086
salbutamol inh. 200-dose package	8.8500	10.9450	11.7700
diclofenac sodium 50-mg ent. tablet	0.4754	0.5209	0.5988
potassium chloride 8 mEq LA tablet	0.0551	0.0616	0.0728
digoxin 0.125-mg tablet	0.0528	0.0715	0.0776
piroxicam 20-mg capsule	0.9823	1.2595	1.5741
amiloride HCl and hydrochlorothiazide 50-mg and 50-mg tablet	0.2694	0.3021	0.3273
diltiazem HCl 60-mg tablet	0.4257	0.5266	0.5848
timolol maleate 0.5% oph. sol.	2.4980	2.6268	2.8457
Interchangeable in 1986[4]			
acetaminophen compound with codeine 30-mg tablet	0.0976	0.0355	0.0375
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	0.0612	0.0462	0.0532
psyllium mucilloid oral pd. 340-g package	6.4000	4.5000	4.7000
naproxen 250-mg tablet	0.2211	0.1430	0.1430
acetylsalicylic acid 650-mg ent. tablet	0.0223	0.0226	0.0259
cimetidine 300-mg tablet	0.0967	0.0891	0.0990
acetaminophen compound with codeine 15-mg tablet	0.0662	0.0319	0.0349
furosemide 40-mg tablet	0.0086	0.0081	0.0089
metoprolol tartrate 50-mg tablet	0.1600	0.1152	0.1268
glyburide 5-mg tablet	0.1069	0.1166	0.1705

1 Highest dollar volume as paid for by the ODB in March 1986. It includes the dispensing fee.

2 The prices in 1987 and 1989 consist of the BAP plus 10 per cent. In 1986, the price is the maximum allowable cost with an allowance for wholesale costs, "unless . . . over 50% of a manufacturer's sales of those drug products in Ontario are via direct channels" [Ontario Ministry of Health 1985a, vii]. Prices are for the first half of the year.

3 By 1989, ranitidine HCl 150-mg tablets, nifedipine 10-mg capsules, diltiazem HCl 60-mg tablets, and timolol maleate 0.5% oph. sol. were all classified as interchangeable. In the table, the BAP plus 10 per cent refers to brands that were single source in 1986 and 1987 – Zantac, Adalat, Cardizem, and Timoptic. Potassium chloride is noninterchangeable. However, since one brand commands virtually all of the ODB market, despite a much higher price, it is treated as a single-source drug. This is the brand whose price is listed here.

4 The lowest price for the interchangeable brands. In some instances, the number of interchangeable brands increased between 1986 and 1989.

Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1986 and 1987; and Ontario Ministry of Health [1989a].

One difficulty in examining prices is deciding which price should be used for the analysis. Before the introduction of the BAP, drug prices in the formulary included a margin of 10 per cent if more than half of the drug was distributed by a wholesaler. After the introduction of the BAP, a margin of 10 per cent was added for reimbursement purposes, regardless of how the drug is distributed. Thus the BAP will already include a distribution margin in some instances and not in others. Since this cannot be determined, we simply compared the formulary price in 1986 with the BAP plus 10 per cent in 1987 and 1989. This is somewhat arbitrary, particularly for interchangeable drugs, which are likely to be distributed directly to the pharmacist. If anything, this comparison will be biased against finding a decline in price for interchangeable drugs, because the 10-per-cent mark-up is included.

Short-Run Impact

The prices of single-source and interchangeable drugs changed substantially between 1986 and 1987; the mean level of the ratio of 1987 to 1986 prices for single-source drugs is significantly higher than that for interchangeable drugs (Table 5-3). The BAP appears to have had, at least in the short run, the desired effect on interchangeable drug prices, consistent with the ministry's claim that "the 'spread' on multiple-source listings was virtually eliminated" [Ontario Ministry of Health 1988c, 12]. It is also consistent with the results in Table 7-1 that the average ODB price for an interchangeable drug fell from $4.59 per claim to $3.35 between the first half of 1986 and the first half of 1987.[7]

The prices of all the single-source drugs in our sample increased between 1986 and 1987 (Table 5-2). While the average increase was 17.7 per cent (Table 5-3), there was considerable variation.[8] The largest price increase – 35.4 per cent – was for digoxin 0.125-mg tablets; the smallest was 9.6 per cent for diclofenac sodium 50-mg enteric tablets. In contrast, all the interchangeable drugs except two fell in price. The average ratio of 1987 to 1986 prices was 76.2 per cent – a substantial decline. Particularly noteworthy were the declines in the prices of the two strengths of acetaminophen compound with codeine, which fell by more than half. Two interchangeable brands increased in price – glyburide 5-mg tablets and acetylsalicylic acid 650-mg enteric tablets. One reason for the increase in the price of glyburide may be the fact that none of the generic firms – Apotex, Horner, and Novopharm – were present to provide price competition.

Long-Run Impact

In the past, attempts to remove the spread have initially led to some reduction in price but have not been permanently effective. The spread has reappeared either because of falling costs or rising prices. Here we investigate only the price side of the equation. The average increase between 1987 and 1989 in the price of the interchangeable drugs was 13 per cent; the average increase in the price of the single-source drugs was 12.7 per cent (Table 5-3). At the 10-per-cent level of significance these differences are insignificant.

In conclusion, there was a once-and-for-all price decrease in the prices of interchangeable drugs, and a once-and-for-all increase in the prices of single-source drugs in 1986/87. Subsequently, their prices increased at much the same rate. This stability is a result of the Ministry of Health's policy of using the CPI as a guide for price increases. It is therefore difficult to draw conclusions based on 1987/89 price comparisons about whether or not the spread has reappeared in the longer run.

Table 5-3

Average change in ODB prices of the 10 highest-dollar-volume single-source and interchangeable drugs, 1986-89

	Mean price ratio[1]	Standard deviation
1987/86		
Single source	1.1767	0.0965
Interchangeable	0.7618	0.0724
1989/87		
Single source[2]	1.1295	0.0624
Interchangeable	1.1265	0.0400

1 The means of the two samples are significantly different for the first panel at 0.01, but not for the second panel at 0.10.
2 Four of these single-source drugs were interchangeable by 1989. The ratio of 1989 to 1987 prices for the sample without these four drugs was 1.1375, not significantly different.
Source Based on Table 5-2.

Ontario's BAP Compared with Saskatchewan's SOC

Another way to assess the effectiveness of the BAP in removing the spread is to compare Ontario prices with those in Saskatchewan, where it is felt that no spread exists. There the price for high-volume interchangeable drugs is set on

the basis of a competitive tender every six months. The winners are awarded standing offer contracts (SOCs) to supply the province's entire needs for that drug for that period (except for no-substitution prescriptions where another brand is specified). That brand is then distributed by approved wholesalers.

In a 1984 study the Ontario auditor compared drug prices for 29 high-volume interchangeable drugs in the two provinces. The study found that Saskatchewan's prices were lower for 27 drugs in 1983 and 25 drugs in 1984. It said that:

> The price of these drugs was in many cases at least twice as much in the Ontario Formulary than in the Saskatchewan Formulary. Despite the fact that a price reduction was effected in the February 1984 Ontario Formulary, we found that 25 of the 29 drugs were still priced higher than in the Saskatchewan Formulary for January 1984, of which 6 were more than 70 per cent higher [Archer 1984, 85].

The 1986 legislative changes in Ontario were motivated by criticisms such as these.

In order to see whether the BAP has eliminated the difference between Ontario and Saskatchewan prices for interchangeable drugs, we carried out a price comparison similar to that carried out by the auditor, but this time for 1989. Of the 10 highest-dollar-volume interchangeable drugs funded by the ODB, three were ineligible.[9] We therefore enlarged the sample so that price comparisons could be made for 10 drugs (Table 5-4). The BAP is compared with the formulary price in Saskatchewan. The price for Ontario is the BAP, for Saskatchewan it is the SOC plus an 11-per-cent distribution charge, since all drugs there must be distributed by wholesalers. The price printed in the Saskatchewan formulary includes the wholesale margin. In Ontario the BAP probably includes the distribution charge to the pharmacist, since interchangeable drugs are typically distributed directly to the pharmacist rather than through a wholesaler.

On average, prices in Ontario were 5.1 per cent higher than those in Saskatchewan. In three cases the price was higher in Saskatchewan than Ontario. The Ontario price was highest relative to the Saskatchewan price for hydrochlorothiazide and triamterene 25-mg and 50-mg tablets. The difference – 28 per cent – was nowhere near the 70 per cent cited by the provincial auditor for 1984. It was lowest for acetylsalicylic acid 325-mg enteric tablets. Overall, the hypothesis that Saskatchewan and Ontario prices were the

Table 5-4

A comparison of formulary prices for the highest-dollar-volume[1] interchangeable drugs, Ontario and Saskatchewan, January-June 1989

Drug, strength, and dosage form	Ontario[2]	Saskatchewan[3]	Ontario/ Saskatchewan price ratio
	(Dollars)		
ranitidine HCl 150-mg tablet	0.7161	0.6716	1.0663
diltiazem HCl 60-mg tablet	0.4350	0.4829	0.9008
diltiazem HCl 30-mg tablet	0.2480	0.2753	0.9008
nifedipine 10-mg capsule	0.3192	0.2898	1.1014
glyburide 5-mg tablet	0.1550	0.1449	1.0697
triazolam 0.25-mg tablet	0.1470	...	...
atenolol 50-mg tablet	0.3890	...	...
acetaminophen compound with codeine 30-mg tablet	0.0341	0.0278	1.2266
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	0.0484	0.0378	1.2804
acetylsalicylic acid 650-mg ent. tablet	0.0235	0.0221	1.0633
furosemide 40-mg tablet	0.0081	0.0075	1.0800
timolol maleate 0.5% oph. sol.	1.9200	...	...
acetylsalicylic acid 325-mg ent. tablet	0.0142	0.0173	0.8208
Mean	...	...	1.0510

1 For Ontario includes the dispensing fee.
2 The lowest BAP as printed in the formulary.
3 The SOC price as printed in the formulary.
Source Ontario Ministry of Health [1989a]; and Saskatchewan Department of Health [1989].

same could not be rejected at the 10 level of statistical significance.[10] This conclusion still holds even if one adds the 10-per-cent margin to the BAP. In conclusion, it appears the inequality of Ontario and Saskatchewan prices recorded in the early 1980s was reduced for the high-dollar-volume interchangeable drugs by the late 1980s.

Several caveats should be borne in mind when interpreting these results. First, Ontario is a relatively large market and Saskatchewan a relatively small one. To the extent that Ontario looks at Saskatchewan prices in setting the BAP, firms may set the same price in both markets rather than quoting lower prices in one market than the other. However, Saskatchewan prices may be of limited relevance in Ontario. The BAP applies to drugs in other parts of Canada that can be purchased in Ontario. The SOC prices are restricted exclusively to Saskatchewan; buying a SOC product for delivery in Ontario is unlikely to result in the SOC price being charged, but a higher one.

Second, the sample of interchangeable drugs, although of substantial importance in dollar terms, comprises only a small number of drugs. ODB officials claim, on the basis of a number of spot checks, that the prices of some interchangeable brands were substantially higher in Ontario than in Saskatchewan. We therefore took the analysis a step further by selecting a sample of SOC interchangeable drugs that included a brand name, a fighting brand, and a generic brand for 1989 (Table 5-5). This sample was chosen because it differed considerably from the one presented in

Table 5-5

A comparison of formulary prices for interchangeable drugs for which there is a fighting brand,[1] Ontario and Saskatchewan, 1989 and 1990

Drug, strength, and dosage form	Ontario[2]	Saskatchewan[3]	Ontario/Saskatchewan price ratio
	(Dollars)		
Panel A: January-June 1989			
ibuprofen 400-mg tablet	0.0640	0.0489	1.31
sulfasalazine 500-mg ent. tablet	0.1251	0.0881	1.42
prednisone 5-mg tablet	0.0098	0.0088	1.11
haloperidol 5-mg tablet	0.1894	0.1266	1.50
erythromycin base 250-mg tablet	0.0510	0.0567	0.90
naproxen 250-mg tablet	0.1300	0.0666	1.95
Mean	...	...	1.37
Panel B: July-December 1990			
ibuprofen 400-mg tablet	0.0640	0.0472	1.36
sulfasalazine 500-mg ent. tablet	0.1313	0.1038	1.26
prednisone 5-mg tablet	0.0098	0.0088	1.11
haloperidol 5-mg tablet	0.1894	0.1127	1.68
erythromycin base 250-mg tablet	0.0530	0.0592	0.90
naproxen 250-mg tablet	0.1300	0.0600	2.17
ranitidine 150-mg tablet	0.7160	0.5495	1.30
triazolam 0.25-mg tablet	0.1260	0.1133	1.11
pindolol 5-mg tablet	0.2872	0.1798	1.60
nadolol 80-mg tablet	0.4621	0.4274	1.08
trimipramine 25-mg tablet	0.1283	0.1360	0.94
Mean	...	...	1.32

1 The sample consists of all those interchangeable drugs for which a fighting brand was present in both provinces, which was an SOC drug in Saskatchewan, and for which there was at least one other brand listed – generally referred to as generic. A fighting brand was defined as one sold by Kenral, Syntex, or Rhodiapharm. If there was more than one dosage form and strength of a drug available, the one with the highest ODB sales in March 1989 was selected.

2 The lowest BAP as printed in the formulary.

3 The SOC price as printed in the formulary.

Source: Ontario Ministry of Health [1989a, 1990b]; and Saskatchewan Department of Health [1989, 1990].

Table 5-4 in terms of the age of the drugs and the mix of brands. If the lowest BAP and the SOC price for this sample were equal, this would substantially strengthen the conclusion drawn from Table 5-4.

The same procedures and time period were used as in Table 5-4. Prices in Ontario, on average, were 37 per cent higher than those in Saskatchewan (panel A, Table 5-5). In all cases except one, the lowest BAP was higher than the SOC price. The only exception was erythromycin base in 250-mg tablets, for which there was no generic brand in Saskatchewan. The lower intensity of competition in the latter province may thus be responsible for the higher price for this drug in that province.

It may of course be that the results in panel A are an aberration.[11] In order to see if this is the case, panel B presents prices for the second half of 1990 for all drugs that include the three brand types (the qualification concerning erythromycin base 250-mg tablets still applies). In this period also, almost without exception, drug prices are substantially higher in Ontario, and the prices of those drugs that appear in both panels exhibited considerable stability over the period. Thus, for drugs where there was a fighting brand, a brand name, and a generic brand, prices were substantially higher – around one third – in Ontario than in Saskatchewan. The Saskatchewan/Ontario difference in price does not necessarily mean that there is a spread in Ontario. Nevertheless, given the magnitude of the difference and its stability through time, it does at least raise the question of whether some portion of the difference indicates the existence of a spread in Ontario.

Third, what is being compared is the BAP in Ontario and the SOC price in Saskatchewan. These prices may not be equal to the average drug costs paid by these provinces' drug plans because no-substitution prescriptions can be written for more expensive brand names. This appears to have been much more of a problem in Saskatchewan than Ontario [Gorecki 1981, 1986c; New Brunswick Commission on Selected Health Care Programs 1989, 73; Saskatchewan Review Committee to the Minister of Health 1989, 21, 51]. The average price paid for all brands of a given drug is probably higher in Saskatchewan than it is in Ontario. However, according to officials in Saskatchewan, the introduction of a copayment on the total price of a prescription in July 1987 resulted in an 18-percentage-point drop in the number of no-substitution claims between 1986 and 1990. In July 1991 the Saskatchewan prescription drug plan stopped paying for no-substitution prescriptions, and it now pays only for the lowest-priced interchangeable product.

Evidence on the Spread

The 10 products whose BAPs were reduced by the Ministry of Health in 1991 included four different drugs: ibuprofen, salbutamol, triazolam, and tamoxifen citrate (Table 5-6). Some of these had leading dollar volumes (see Table 7-2). The products with imposed BAPs were marketed by three firms: Apotex, Novopharm, and Rhone Poulenc Pharma. However, there were interchangeable brands of all these drugs that did not have imposed BAPs.

The new BAPs for the 10 drug products appeared in the February 1991 formulary but they were made retroactive to the last half of 1990. We can therefore determine the magnitude of the spread for this latter period by comparing the published BAPs in the July 1990 formulary with the imposed BAPs. The spread is defined, initially, as the difference between a brand's BAP, based on data submitted by the firm, and the imposed BAP, expressed as a proportion of the former (Table 5-6, column 4).

Using this definition, the results suggest that the spread on these 10 drug products was substantial, averaging 26.2 per cent. These estimates of the spread are likely to be biased upward. For a group of interchangeable drugs, the ODB will pay no more than the lowest BAP for that group of products (column 3). Furthermore, if a firm's drug product has a published BAP that is higher than the lowest BAP, the firm will frequently inform the ministry that it has reduced its BAP to match the lowest. Using this BAP rather than that based on data submitted by the firm, the spread on these 10 drug products was still substantial, averaging 21.7 per cent (column 5).

The evidence in Table 5-6, consistent with the results of the comparison of Saskatchewan and Ontario prices, indicates that the spread is largely confined to those drugs which have a brand name, a generic brand, and a fighting brand. Almost all the drugs whose BAPs were imposed include all three brands. The exceptions are ibuprofen in 200-mg tablets, which has no brand name, and tamoxifen citrate in 10-mg tablets, which has no fighting brand.

There are a number of possible explanations for this. In all instances except one – Tamofen – it was a generic drug firm that had its BAP reduced as a result of the Ministry of Health inspections, not firms marketing fighting brands. It could be that the generic firms, in their attempt to limit the market-share gain of the fighting brands, cut their prices so aggressively below the lowest BAP that detection became relatively easy.

Another possible explanation is that over the years the generic firms have developed the game of playing the spread

Table 5-6

Estimates of the spread on the ODB prices of interchangeable drugs, July 1990 to February 1991

	Best available price			Spread[3]	
	Submitted by firm[1] (1)	Imposed by Ministry of Health[2] (2)	Lowest in formulary[1] (3)	[(1) – (2)]/(1) (4)	[(3) – (2)]/(3) (5)
	(Dollars)			(Per cent)	
Drug, strength, and dosage form[4]					
ibuprofen 200-mg tablet (3)					
Apo-Ibuprofen	0.0365	0.0308	0.0365	15.6	15.6
ibuprofen 300-mg tablet (4)					
Apo-Ibuprofen	0.0516	0.0370	0.0493	28.3	24.9
Novo-Profen	0.0516	0.0370	0.0493	28.3	24.9
ibuprofen 400-mg tablet (4)					
Apo-Ibuprofen	0.0670	0.0480	0.0640	28.4	25.0
ibuprofen 600-mg tablet (4)					
Apo-Ibuprofen	0.0855	0.0612	0.0816	28.4	25.0
Novo-Profen	0.0855	0.0612	0.0816	28.4	25.0
salbutamol inh. 200-dose package (3)					
Apo-Salvent	8.4000	6.0000	8.0000	28.6	25.0
triazolam 0.125-mg tablet (3)					
Apo-Triazo	0.1066	0.0763	0.1018	28.4	25.0
triazolam 0.25-mg tablet (4)					
Apo-Triazo	0.1319	0.0945	0.1260	28.4	25.0
tamoxifen citrate 10-mg tablet (5)					
Tamofen	0.6740	0.5435	0.5500	19.4	1.2
Mean	...	...	...	26.2	21.7

1 As published in the July 1990 formulary.
2 As published in the February 1991 formulary.
3 The difference between the listed price and the actual firm selling price, expressed as a percentage of the listed price. The listed price is in columns 1 and 3, the actual price is in column 2.
4 Numbers in parentheses are the number of interchangeable drug products in the July 1990 formulary.
Source Ontario Ministry of Health [1990*b*, 1991]; and letter dated 20 February 1991 to Ontario pharmacists accompanying the February 1991 formulary from the director of the ODB.

to a fine art. It was easy to predict the BAPs because they were geared to the CPI. Behind this facade, as they competed for shelf space, the firms offered secret discounts – some price, others nonprice – to pharmacists on a wide range of interchangeable drugs. The fighting brands upset the status quo by charging lower BAPs rather than using secret discounts and inducements. The lowest BAP in the July 1990 formulary for all the drugs in question was set by the fighting brand. Although the spread may exist on many interchangeable drugs, the presence of the fighting brand causes a disequilibrium to develop, thus making detection of the spread easier.

Whither the Spread?

It appears that the introduction of the BAP system of drug pricing resulted in a substantial reduction, if not elimination, of the spread in 1986/87. But in the longer run it appears that the spread has re-emerged, although the evidence is somewhat ambiguous. It is true that in 1989 in Saskatchewan – a province where there is said to be no spread – the prices of the highest-dollar-volume interchangeable drugs were the same as those in Ontario. Nevertheless, in instances where there was a fighting brand, a brand name, and a generic brand, the evidence suggests that there was a spread.

Furthermore, there is also evidence, albeit not quantitative, that the spread has re-emerged in Ontario. For example, the Pharmaceutical Inquiry of Ontario said that "The Committee was . . . told about the increasing spread which has entered the pricing system under the current BAP negotiated reimbursement system" [1990*a*, 70].[12]

Beyond the BAP: Are There Better Alternatives?

It appears that history is repeating itself. The two previous attempts to eliminate the spread in 1979 and 1984, while initially successful, saw its eventual reappearance. This is not altogether surprising considering the incentives created in the marketing of interchangeable drugs under a BAP system. In order for the system to result in low prices to the ODB, it must include the appropriate incentives, which the current system does not. Before considering reforms, therefore, it is important to understand the shortcomings of the present system.

There are a number of alternatives to the BAP system. Several are considered here, some that would involve minor adjustments and others that would entail major changes. Various provinces have either experimented with them or currently use them. The experience of British Columbia, New Brunswick, Nova Scotia, and Saskatchewan will be drawn upon here. Attention is also paid to the regulatory approach advocated by the Pharmaceutical Inquiry of Ontario [1990*a*].

The Problem with the BAP: Incentive Incompatibility

Any set of pricing rules will have great difficulty attaining its goals if it does not utilize the wealth-maximizing motivation of pharmacists, wholesalers, and drug firms. In other words, in order to be efficient and workable, a system must accomplish its objective by expecting each participant to do what is in its own best interest. A system that requires participants to act contrary to their interests is unlikely to succeed. It makes little sense to design a system that does not take into account participant motivation, and then blame any failure on their dishonesty.

Where interchangeable drugs are concerned, what determines success in the marketplace is price. In the context of the ODB, this is the price to the pharmacist, not the BAP. The BAP is a forecast of the price at which manufacturers intend to sell their product several months in the future. If this turns out to be higher than the lowest interchangeable BAP, then the firm will frequently submit a revised price to the Ministry of Health to match the lowest BAP.

With several interchangeable brands selling at the lowest BAP, how can the pharmacist select one brand over another, or the drug firm secure an extra pharmacy account? It is not surprising that these conditions give rise to incentives for free goods, secret discounts, and free gifts such as televisions, bar fridges, propane barbecues, electric staplers, and trips to holiday resorts. Eventually the spread reappears. The situation can be likened to a price-fixing agreement in which the lowest BAP is the agreed upon price. Under such conditions there are powerful incentives to price-discount.

Under the present ODB pricing system, the BAP is the lowest price at which that product is available. Publication of this price puts pharmacists on notice that the product is available at this price, so they will insist on receiving this price or better. Furthermore, a drug firm can only win a particular pharmacy account by offering a lower price or some other incentive. However, this must remain secret or it becomes the new BAP and must be offered to all.

In addition to removing the spread, reform of the ODB also needs to take into consideration the relationship between the ODB and non-ODB markets, since evidence suggests that the BAPs in the provincial formulary become guidelines for prices charged in the non-ODB market (see Chapter 3). Frequently the non-ODB price and product selection rules, whether legislated or negotiated by private, third-party drug plans, do not require that the lowest BAP be charged for a group of interchangeable brands. Furthermore, the 10-per-cent margin on top of the BAP provides an incentive to dispense brands with higher BAPs.

Within these confines, the pharmacist has some discretion in brand selection. There is an incentive for firms to list their brand's price on the high side in the formulary and then sell low, so that pharmacists will dispense their brand. Manufacturers improve the saleability of their products by making them more valuable to their customers, the pharmacists. In other words, there is a spread in the non-ODB market that is perpetuated by publishing the BAPs of all interchangeable brands in the formulary rather than just the lowest (the one used for ODB reimbursement purposes).

The spread in both the ODB and non-ODB markets arises because of normal competitive pressures as drug firms and pharmacists seek to maximize returns. Drug firms gain market share and higher profits by offering pharmacists lower prices than their competitors are offering, and pharmacists, by seeking out the lowest-priced suppliers, increase their income through the difference between the ODB

reimbursement price and the acquisition cost. How can these motivations be utilized in such a way that lower prices result to the ODB and non-ODB markets, while still preserving enough of an incentive for pharmacists and drug firms to engage in competitive behaviour?

Minor Adjustments: Market-Assessed Price, Price Monitoring, and a Single Formulary Price

There are several ways that the present system could be adjusted without making major changes; for example, a BAP combined with a competitive dispensing fee, a BAP with a rebate scheme, and a market-assessed price (MAP) with price monitoring and a single formulary price. The latter has the best chance of utilizing the incentives of the participants in such a way that the spread is reduced and prices are lowered. Furthermore, it is consistent with the competitively set dispensing fee favoured in Chapter 4.

Market-assessed pricing of interchangeable drugs would retain the present ODB pricing and product selection rules, but with the following new elements:

- One formulary price and no automatic mark-up – The formulary would contain only a single price for a group of interchangeable drugs. The 10-per-cent mark-up would be abolished, except for drugs distributed through a wholesaler.[13] The objective of this condition is to decouple the ODB and non-ODB markets and so reduce the role of the formulary in promoting the dispensing of higher-priced brands.

- Market-assessed price — The price listed in the formulary would be that at which the pharmacies that account for 90 per cent of claims volume in Ontario can purchase the drug. This condition would ensure that the price set is generally available in Ontario. If smaller pharmacies have difficulty buying at the MAP, then a payment can be made. This condition introduces incentives for pharmacies to realize scale economies in buying.

- Legitimatizing market forces — Drug firms would be allowed to offer prices below the MAP and pharmacists would be allowed to accept such prices. Manufacturers would be encouraged to sell at prices below those listed, and pharmacists encouraged to negotiate lower prices by permitting them to keep the full benefit of prices below the lowest MAP for a group of interchangeable drug products. For administrative purposes, free goods and gifts would be prohibited, with stiff penalties should they be offered or accepted. This condition would facilitate the normal buyer-seller interaction that characterizes competitive markets.

- Determining the MAP — ODB officials would carefully monitor prices by examining a variety of sources: prices submitted by firms, prices prevalent in other jurisdictions in Canada and those recorded by Intercontinental Medical Statistics (a firm that surveys drug prices), and by paying individual pharmacists to provide information and audit other pharmacists. These pharmacists would be carefully selected to ensure that they are representative of the regions of Ontario and the store-size distribution. High-dollar-volume interchangeable drugs, where the spread is particularly likely to exist, would be monitored. There are a number of situations where this might occur. For example, a new entrant might lead to a reduction in the price of a drug. We have shown that where a fighting brand, a brand name, and a generic brand were present, there was a substantial difference between prices in Ontario and Saskatchewan, perhaps signifying a spread. Nontrivial shifts in market share may signal active price competition. Once there is a substantial and permanent reduction in price, then the ODB can lower the MAP. No compensation would be paid to pharmacists. The objective of this condition is to provide the framework within which the MAP can be determined, and also incentives for drug firms and pharmacists to engage in competitive behaviour that results in lower prices for interchangeable drugs to the ODB. The fact that the MAP is reduced with a lag would give pharmacists a period in which they can reap a reward from purchasing at lower prices than the MAP, while drug firms can increase their market shares. Furthermore, given the pressure on health-care costs, the ODB will probably have sufficient motivation to lower MAPs when appropriate.

- Administration — The lower MAP could be communicated to pharmacists and manufacturers by means of a supplementary bulletin to the formulary, perhaps on a monthly basis. This bulletin could also list additional products approved by the Drug Quality and Therapeutics Committee. Once or twice a year these bulletins could be consolidated in a separate edition of the formulary.

The success of the MAP scheme depends on how diligently prices are monitored and the detection of permanent and substantial reductions in price. These need to be carefully distinguished from temporary price wars. At first then, only the largest and most enduring differences between the published MAP and the price paid in the marketplace should result in price reductions by the ODB. As the ODB gains confidence and experience, others could be examined.

Some would argue that the biggest drawback of the price monitoring approach is that it involves a much more active government role, one that government is inherently unsuited to play. However, the Ministry of Health has recently taken

a much more active role in inspecting drug firm and pharmacy records, so it is not at all clear that it would be unsuited to such a task. As the payer of the ODB, it has a strong incentive to pay lower prices. Furthermore, it has had a pharmacy auditing function since the creation of the ODB.

The MAP is not a complete panacea. The system would require careful monitoring with respect to prices and free goods, and active enforcement would be necessary. Even then, problems would still occur. For example, pharmacists might demand compensation every time a price is dropped. This would have to be resisted firmly, since it would clearly defeat the purpose of the exercise. Nevertheless, a MAP-based system has a more appropriate set of incentives than the present BAP system and should thus ensure lower prices for interchangeable drugs.

Actual Acquisition Cost: A More Far-Reaching Change

Another method of setting prices and reimbursing pharmacists that has garnered much attention is actual acquisition cost (AAC). It applies equally well to both single-source and interchangeable drugs. It has had the consistent support of the Pharmaceutical Manufacturers Association of Canada [1988*a*, 1988*b*], which represents the large multinational drug firms that dominate the industry and introduce virtually all new drugs. Several members of that association are also on record as supporting the AAC, including Astra Pharma [1988], Boehringer Ingelheim (Canada) [1988, 15], Glaxo Canada [1988, 6], and Merck Frosst Canada [1988, 6]. A number of provinces, including British Columbia, New Brunswick, Nova Scotia, and to a lesser extent Saskatchewan have introduced the AAC pricing, and British Columbia and Saskatchewan still retain it. Attention will be confined here to the experience of one province that experimented with the AAC, Nova Scotia, and one that still retains it, British Columbia.[14]

In the AAC system, government, as such, does not set the price. A formulary listing eligible benefits and/or interchangeable brands may or may not be published. Nova Scotia's formulary is a listing of interchangeable products, not a benefits list, and British Columbia does not publish a formulary at all.[15] The choice of interchangeable brand is largely at the discretion of the pharmacist – except in those cases where the physician specifies that a certain brand must be dispensed. Typically, however, there is a rule that *if* the pharmacist selects a different brand from that prescribed, it must be lower priced than that prescribed – perhaps the lowest in his/her inventory or merely lower in cost. The claim the pharmacist sends to the drug plan for reimbursement is the actual acquisition cost of the drug, typically net of special rebates and other monetary and nonmonetary inducements paid by drug firms. Thus the price of the drug product can vary from pharmacy to pharmacy. The government carefully monitors the prices submitted, perhaps identifying exceptionally high claim prices and making appropriate inquiries (unless of course there is some obvious explanation; for example, the pharmacy is small and remote, and orders in small lot-sizes).

There are several advantages to the AAC system, claim its advocates. It gets the government out of the business of setting prices, since this is done in the marketplace where the forces of competition will result in the lowest prices possible and the abolition of the spread. Small pharmacies that service remote areas can stay in business. Furthermore, the pharmacist can select the brand on the basis of the best therapeutic interests of the patient rather than personal gain through price-spreading [Pharmaceutical Manufacturers Association of Canada 1988*b*]. Thus the AAC system promises lower administrative costs, greater reliance on market forces, lower drug prices, and removal of the spread.

There are, nevertheless, a number of problems with the AAC system that cast doubt on the degree to which it would result in lower expenditure for the ODB. The incentive for a price-spread exists under both the BAP and the AAC, since the pharmacist makes crucial decisions as to brand choice under both systems. Indeed, it could be argued that the incentive for the spread under the AAC is greater and more pervasive. Under the BAP system the spread performs one major function for interchangeable drugs: to allocate market share among a group of two or more lower-priced brands, for which the spread is used as a way to compete for shelf space in the pharmacy. When there is only one lower-priced brand, the firm has no need to offer the spread, since the BAP system ensures that the brand has virtually all of the market (see Table 5-8).

However, under the AAC the spread performs an additional function: it provides an incentive for pharmacists to product select the low-priced brands. In other words, faced with one high-priced brand, which is the norm for prescribing and dispensing, and a lower-priced new entrant, the spread provides a motivation to overcome the inertia and brand loyalty to the higher-priced originator brand.

Thus under the AAC there is an incentive for the spread to exist where there are one or more lower-priced interchangeable brands, but under the BAP there is an incentive only when there are *two* or more. The reason for the spread in both cases is that the pharmacist has a decisive

influence over brand choice. The difference between the BAP and the AAC is that under the BAP the pharmacist is compelled to select a low-priced brand, while under the AAC it is at the discretion of the pharmacist whether a high- or low-priced brand is selected.[16]

Suppose, however, that the spread were eliminated through diligent monitoring of claims and stiff penalties for the submission of inflated claims. Under these conditions there would be little incentive for the pharmacist to product select the lower-priced brand. For recently launched drugs, most prescriptions are likely to be for the higher-priced originator brands and there are likely to be some no-substitution prescriptions. Therefore, the pharmacist would probably have to stock the higher-priced brand. As such there is little incentive to carry the low-priced competitor, for which demand is likely to be limited. Inventory costs are likely to be higher carrying two brands rather than one. However, as the drug becomes older, and experience with the lower-priced brand increases, brand loyalty may decline and more demand may be generated for the lower-priced brand. The drug becomes a commodity, and there is little brand loyalty to the leader. In this situation one would expect that penetration by lower-priced brands under an AAC system would initially be lower than under a BAP system, but that the difference would tend, for any given drug, to diminish over time.

Hence, although the AAC may eliminate the spread, if high-priced interchangeable brands retain their market share, it might result in average prices for interchangeable drugs that are higher than under the BAP even with a spread. In addition, to the extent that the AAC system does not encourage good buying practices, prices might be inflated due to sloppy inventory control or the purchase of small lot-sizes. The AAC system provides no incentives for the pharmacist to make cost-minimizing choices.

The AAC, the BAP, and the Spread

To consider the relationship between the spread and the BAP and AAC pricing systems more formally, let us assume that there are only two interchangeable brands. One is the higher-priced originator brand, the other is the lower-priced generic brand. However, the latter could also be representative of all lower-priced brands, where there is more than one.

The ODB price under the BAP system is defined as:

$$P_{odb} = (1 + s)P_1 \qquad (5.1)$$

where

P_{odb} = the average price paid by the ODB for a group of interchangeable drug products, the lowest BAP;
s = the spread, defined as the mark-up over P_1 expressed as a proportion; and
P_1 = the actual acquisition cost to the pharmacist of the lowest-priced BAP.

This assumes that the lower-priced brand captures the whole market and/or that any brand-name sales are at P_1.

The calculation of the price paid under the AAC system for the same interchangeable drug is somewhat more complicated:

$$P_{aac} = (1 - e)P_1 + eP_p \qquad (5.2)$$

where

P_{aac} = the average price paid under an AAC system for a group of interchangeable drug products;
e = the proportion of the quantity of the interchangeable drug accounted for by the brand-name product; and
P_p = the actual acquisition cost to the pharmacist of the high-priced originator brand.

The AAC price is thus the weighted average of the higher-priced and lower-priced brands, with the weights being the market share of each brand. Under the BAP system the originator's market share is assumed to be zero. Furthermore, it is assumed that P_1 is the same under both the AAC and BAP systems.

The spread can be derived in terms of e, P_p, and P_1, by setting P_{odb} equal to P_{aac} and solving for s. The result is:

$$s = e\,(P_p/P_1 - 1). \qquad (5.3)$$

The spread that can exist under the BAP with no difference in BAP and AAC prices per drug varies directly with e and P_p/P_1. By taking not unreasonable values of e, P_p, and P_1 for the early 1980s for a sample of seven high-volume interchangeable drugs, the value of s was 1.31.[17] In other words, the BAP spread or mark-up could be 131 per cent of the pharmacist's acquisition cost of the drug, P_1, and the average price paid by the ODB and the AAC system would be the same.

Advocates of the AAC system can thus claim that it will remove the spread and lower the prices of individual brands of a drug to the government – although only where the

number of lower-priced interchangeable brands is greater than one. However, it would be incorrect to infer from this that the AAC system is necessarily better than the BAP. This depends, as shown above, on the market share of the originator and its price relative to the lower-priced interchangeable brand.

Resolution — The AAC system is in one sense naive, in that it does not consider the incentives under which pharmacists and drug firms operate. Recently, more sophisticated AAC systems have attempted to resolve these difficulties by providing incentives for pharmacists to product select. In Nova Scotia, pharmacists were given a $0.50 incentive payment every time they product selected; in British Columbia pharmacists were given 20 per cent of the difference between 110 per cent of the highest-priced brand price and the AAC billed to Pharmacare.[18]

Drawing on the earlier notation, the AAC price with product selection incentives can be written as follows:

$$P_{aac'} = (1 - e')P_1 + e'P_p + (1 - e')g \quad (5.4)$$

where

$P_{aac'}$ = average price paid under an AAC system with product selection incentives for a group of interchangeable drug products;

e' = the proportion of the quantity of the interchangeable drug accounted for by the brand name with product selection incentives; and

g = a fixed dollar payment every time product selection takes place, as was introduced in Nova Scotia.

It is assumed that the incentive payment reduces the patentee market share, with the relationship between e' and e being:

$$e' = e(1 - b). \quad (5.5)$$

In other words, the originator's market share is reduced by b, which can vary between zero and unity. It is further assumed that all sales of the lower-priced brands involve product selection, hence the term $(1 - e')g$.

In order to determine the impact on the price paid under an AAC system with and without product selection incentives, equation 5.5 can be substituted into equation 5.4, and, after some manipulation, it can be derived that:

$$P_{aac'} = P_{aac} + eb(P_1 - P_p + g) + g(1 - e). \quad (5.6)$$

Prices fall with the introduction of the product selection incentive payment if:

$$g(1 - e) - eb(P_1 - P_p + g) > 0. \quad (5.7)$$

The first term must be positive and represents the incentive payment paid on that portion of product selection that occurred prior to the introduction of the incentive payments. The second term represents the change in expenditure on the originators brand. This will be negative if:

$$g < P_p - P_1. \quad (5.8)$$

In other words, the incentive payment must be less than the price difference between the lower- and higher-priced brands.

Determining how effective the product selection incentive payment system would be requires knowing the elasticity of pharmacists' propensity to product select with respect to the incentive payment. In turn, this depends on pharmacists' and physicians' loyalty to the higher-priced originator brand. Furthermore, no response by the brand-name firm to the introduction of the incentive payment system has been assumed, which may not be the case. If the incentive payment is a fixed dollar amount that is quite small in relation to the price of the higher-priced brand, then the brand-name firm may find it profitable to offer secret discounts to retain market share. In other words, the drug plan and the brand-name firm have a bidding contest for market share, the result of which may not benefit the public purse.

Nova Scotia Pharmacare[19]

The population eligible for Nova Scotia Pharmacare is similar to that eligible for the ODB. These two drug plans started at about the same time, in 1974. However, they differ in many respects, including – at least for some periods – the pricing of drugs.

Nova Scotia Pharmacare has taken three approaches to setting drug prices for the purposes of reimbursement. These are:

- Prior to July 1986 a formulary (which had existed since 1976) listed only interchangeable brands. Pharmacists were reimbursed for the brand dispensed on the basis of "defined cost." This was typically based on the list or catalogue price for smaller package-sizes, except for some high-volume interchangeable drugs, whose prices were based on larger package-sizes. Some prices were frozen in the two

years prior to July 1986 because the list prices were higher than the prices paid by pharmacies. Product selection was permissive and was not introduced until 1983, in part because of opposition from physicians. There was no patient/consumer copayment.

- Between July 1986 and May 1990 the basis for reimbursement became the actual acquisition cost, defined as net cost to the pharmacist after deducting rebates, allowances, free products, and so on. The AAC claims were monitored, and when they were high by some reference standard, an inspection of pharmacy records might be carried out. Product selection was still permissive. As of July 1987 pharmacists were paid an incentive payment of $0.40 (raised to $0.50 a year later) every time such selection took place.

- In June 1990 the basis of reimbursement for interchangeable drugs became a single maximum allowable cost (MAC) for all brands, based on the average acquisition cost of the lower-priced brands. Irrespective of the interchangeable brand dispensed, the MAC was all that Pharmacare would reimburse the pharmacist. When submitting claims, pharmacists could list either their actual acquisition cost or the maximum allowable cost. The incentive payment of $0.50 was abolished, but the dispensing fee was increased. A fixed $3 patient/consumer copayment per prescription was also introduced, with a limit of $150 per year per person. Thus, after a four-year experiment, Nova Scotia replaced the AAC with a system similar to Ontario's.

According to Anis [1989], the introduction of the AAC in Nova Scotia led to a decline in the prices of interchangeable brands, but it had little impact on the prices of single-source products. The fall in the price paid by Pharmacare was estimated to be about one third. The changes were measured in both the short run (April-June to October-December 1986) and longer run (April-June 1986 to October-December 1987). This result is similar to what occurred in Ontario with the introduction of the BAP in 1986.

Despite the decline in the prices of interchangeable brands, the Nova Scotia Royal Commission on Health Care clearly felt that not enough of the market for interchangeable products was held by lower-priced brands. Its report comments that:

> Some calculations indicate that over $3 Million in savings could be realized each year with a lowest-available price drug product programme. The current incentive for generic drug substitution is only marginally effective in encouraging the use of generic substitutes for brand name drugs. The price paid by pharmacists, or actual acquisition cost of drugs can be higher than best open-market price, a problem which Ontario has dealt with successfully by negotiating with manufacturers directly [1989, 115].

The commission offers no explanations for why the incentive for product selection was ineffective. Had the originator, for example, offered pharmacies more than $0.50 to preserve its market share? Nor does it elaborate on the suggestion in the final sentence that the spread still exists in Nova Scotia.

The commission recommended that the Ministry of Health abolish the AAC and "mandate a lowest-available price-product system for the Pharmacare Programme" [1989, 117]. There was no discussion of other alternatives such as a better or more generous product selection incentive. The policy of June 1990 implemented the commission's recommendation. Pharmacare says preliminary indications are that drug costs have been contained.

The Long View: 1983-90 — There have been a number of significant changes in Pharmacare's price and product selection rules for interchangeable drugs. The AAC system led to a reduction in prices of generic brands, but it probably had little impact on their market share, while the MAC system – if the ODB is any guide – will increase the market share of generic brands and consequently lower drug costs.

Looking at the data for the period, there was substantial variation in virtually all of the indicators of price, market share, and importance (Table 5-7). The most notable exception is the prescription volume accounted for by interchangeable drugs, which was relatively constant at between 40 to 45 per cent. These variations are, by and large, consistent with the predictions and results reported above. The introduction of product selection legislation was associated with a reduction in potential and actual drug costs and an increase in the generic market share from less than 2 per cent to nearly 25 per cent.

The fall in average actual drug costs from $9.15 to $8.11 between April and June of 1986 and 1987 indicates that AAC pricing led to a drop in the prices of interchangeable drug products, which is consistent with the study reported above, although the magnitude reported here is less. However, the AAC appeared to do little to raise the market share of generic brands, which would lower costs for interchangeable drug products even further. This was the conclusion of the Nova Scotia Royal Commission on Health Care [1989]. It is difficult to evaluate the impact of the $0.40 and $0.50 incentive payments.[20] The $0.40 incentive payment was associated with a 5-percentage-point gain in the generic market share; the increase to $0.50 seems to have had little impact.

Table 5-7

The impact of various policy changes on Nova Scotia Pharmacare's drug costs, and the market share of generic drug manufacturers, selected periods, 1983-90

	Prescriptions for interchangeable drug products				
	As a proportion of all pharmacare prescriptions (1)	Average drug cost		Difference [(2) – (3)]/(3) (4)	Proportion accounted for by generic drug manufacturers[3] (5)
		Actual[1] (2)	Potential[2] (3)		
	(Per cent)	(Dollars)		(Per cent)	
Time period					
April-June 1983	45.3	9.34	6.90	35.3	1.9
July 1983: product selection legislation					
April-June 1984	43.5	7.84	5.80	35.1	24.5
April-June 1986	43.8	9.15	6.25	46.4	24.6
August 1986: actual acquisition cost					
April-June 1987	42.7	8.11	5.00	62.2	23.9
July 1987: $0.40 premium for product selection					
July-September 1987	42.3	8.14	5.06	60.8	28.5
October-December 1987	41.5	8.22	5.13	60.3	30.8
January-March 1988	40.8	8.03	5.07	58.4	32.4
April-June 1988	42.8	10.60	6.90	53.8	31.6
July 1988: $0.50 premium for product selection					
July-September 1988	42.4	10.68	7.01	52.2	31.8
October-December 1988	43.5	12.22	8.33	46.7	31.6
January-March 1989	43.0	12.20	8.46	44.2	31.9
April-June 1989	45.3	14.41	10.36	39.1	31.0
July-September 1989	45.1	14.49	10.46	38.5	31.6
October-December 1989	45.0	14.84	10.81	37.2	31.8
January-March 1990	43.9	14.40	10.48	37.5	32.3
April-June 1990	45.9	14.44	11.08	30.3	39.2
June 1990: maximum allowable cost					
July-September 1990	45.3	11.44	11.30	1.3	75.0

1 Average cost of all interchangeable drug products.
2 Each prescription is repriced using the lowest-cost brand with which it is interchangeable. The mean drug cost of all prescriptions for interchangeable drug products is then calculated.
3 The market share held by Apotex, ICN Canada, Kenral, Novopharm, Syncare, and Technilab.
Source Based on data supplied by Maritime Medical Care.

The MAC system led to a substantial expansion in the market share of generic brands – more than 30 percentage points – and the virtual elimination of the difference between the actual and potential mean drug cost per prescription, which were both slightly more than $11 in the period July-September 1990. Further reductions in drug cost can only come about if the MAC is too high and/or there is a spread.

B. C. Pharmacare[21]

In contrast to the ODB, B.C. Pharmacare, founded in 1974, provides varying degrees of coverage for the whole of the population. For example, since 1987, those aged 65 and over pay 75 per cent of the dispensing fee up to an annual cumulative maximum of $125 per person, and those under 65 pay $325 per family plus 20 per cent thereafter, with a cumulative annual maximum of $2,000 per family.

B.C. Pharmacare has used AAC pricing since at least 1977. Claims are carefully monitored, and inducements investigated.[22] Where appropriate, pharmacies repay Pharmacare if they overbill.[23] Product selection is permissive where the price to the purchaser of the selected drug is no more than the price of the prescribed brand.

Ontario's BAP and British Columbia's AAC: A Comparison — According to Gorecki [1986c], in 1983 the prices for a sample of seven high-dollar-volume interchangeable drugs were lower in British Columbia than they were in Ontario. This appears to be primarily due to the presence of the spread in Ontario. In the first formulary of 1984, however, Ontario introduced more realistic prices for these seven drugs, eliminating the price difference.

We compared British Columbia's AAC and Ontario's BAP using a larger sample of high-dollar-volume interchangeable drugs for 1989 (Table 5-8). The average market share of the lower-priced brands in Ontario, at 84.8 per cent, was clearly much higher than British Columbia's 35 per cent.[24] This difference is particularly marked for drugs that were made interchangeable in Ontario in the first six months

Table 5-8

Drug prices and market shares, B.C. Pharmacare and Ontario Drug Benefit, highest-dollar-volume interchangeable drugs,[1] 1989[2]

	Market share of lower-priced brand[3]		B.C./Ontario price ratio			Ratio of higher-priced to lower-priced brand	
	British Columbia (1)	Ontario (2)	Higher-priced brand (3)	Lower-priced brand[4] (4)	B.C./Ontario price ratio for the drug[5] (5)	British Columbia (6)	Ontario (7)
	(Per cent)						
Drug, strength, and dosage form							
ranitidine HCl 150-mg tablet	56.1 (1)	89.5 (1)	1.0004	0.9630	1.0908	1.3595	1.3086
diltiazem HCl 60-mg tablet	3.0 (1)	89.3 (1)	1.0803	1.0175	1.3019	1.2976	1.2221
diltiazem HCl 30-mg tablet	3.9 (1)	89.9 (1)	1.0825	1.0004	1.3000	1.3220	1.2218
nifedipine 10-mg capsule	30.6 (2)	89.2 (2)	0.9842	1.0454	1.2688	1.3857	1.4486
glyburide 5-mg tablet	18.8 (1)	24.5 (1)	1.0102	0.9503	1.0103	1.0794	1.0148
triazolam 0.125-mg tablet	1.5 (2)	77.3 (1)	1.0236	0.9394	1.1632	1.2446	1.1423
atenolol 50-mg tablet	10.2 (1)	85.3 (1)	1.0285	0.9748	1.2571	1.3415	1.2715
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	45.5 (2)	93.8 (2)	0.4152	1.0000	1.1323	1.4256	3.4339
acetylsalicylic acid 650-mg ent. tablet	13.1 (4)	79.3 (1)	2.0837	1.1362	2.1695	2.0524	1.1191
furosemide 40-mg tablet	72.0 (4)	97.6 (5)	1.0498	1.0357	3.5870	10.8966	10.7500
timolol maleate 0.5% oph. sol.	7.0 (1)	85.9 (1)	0.9487	0.9632	1.1934	1.3245	1.3474
naproxen 250-mg tablet	91.5 (3)	98.2 (3)	0.9368	1.0163	1.0355	3.0036	2.5770
cimetidine 300-mg tablet	78.6 (3)	91.9 (3)	0.9838	1.0279	1.3943	3.6879	3.8530
methyldopa 250-mg tablet	57.8 (3)	95.7 (4)	1.0099	1.0215	1.5766	2.3112	2.3377
Mean	35.0 (2.1)	84.8 (1.9)	1.0455	1.0065	1.4630	2.4094	2.4320

1 The highest-dollar-volume interchangeable drugs among the 32 highest-dollar-volume drugs paid for by the ODB in March 1989. Naproxen, cimetidine, and methyldopa were included because they were used in an earlier work comparing British Columbia and Ontario.
2 The ODB data are for March 1989, and the Pharmacare data for January-March 1989.
3 Market share measured in number of tablets or capsules. The numbers in parentheses are the number of lower-priced brands.
4 Where there were more than one brand, the weighted average was taken. The weights were quantity.
5 Average price paid for all brands.
Source Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989; data supplied by B.C. Pharmacare; and Gorecki [1986c, 108, Table 5].

of 1989 – diltiazem 30-mg and 60-mg tablets, triazolam 0.125-mg tablets, and atenolol 50-mg tablets. For these four drugs the lower-priced brands accounted for 85.5 per cent of the market in Ontario and 4.7 per cent in British Columbia.

Turning to the Ontario/B.C. price ratios for the higher- and lower-priced brands, there is always one higher-priced brand, and it is the same in the two provinces. The numbers in parentheses in columns 1 and 2 are the number of lower-priced brands paid for by each plan. Sometimes a particular lower-priced brand appears only in British Columbia or Ontario. For example, the Drug Trading Company sells brands of furosemide and methyldopa in Ontario but not in British Columbia.[25] In estimating the price ratios, the lower-priced brands are the weighted average of all lower-priced brands, where the weights are quantities sold.

The prices of the lower- and higher-priced brands are much the same in British Columbia and Ontario (columns 3 and 4).[26] There are two noticeable exceptions: for hydrochlorothiazide and triamterene 25-mg and 50-mg tablets the higher-priced brand is priced substantially lower in British Columbia than Ontario, and for acetylsalicylic acid 650-mg enteric tablets the reverse is true. These results suggest that drug firms set the same prices Canada-wide.

It is clear from column 5 that the prices paid in British Columbia are consistently higher than those paid in Ontario, some by as much as 360 per cent.[27] On average they are 46 per cent higher. This is not surprising, given the similarity in the provinces' brand prices, the difference between the higher- and lower-priced brands in both provinces (columns 6 and 7), and the much higher market share of the lower-priced brands in Ontario.

The market share of the lower-priced brands in Ontario underestimates the influence of these products on the prices paid. The lowest BAP sets the price for all brands, unless no-substitution is written on the prescription. In other words, if the higher-priced brand is dispensed for a prescription on which no-substitution in not indicated, then the pharmacist will only receive the lowest BAP for that interchangeable group of products. We re-estimated column 2 to be the market share for which the lowest BAP set the price. In this scenario, that market share never fell below 90 per cent, and sometimes exceeded 99 per cent, with a mean value of 96 per cent.

One caveat needs to be borne in mind when comparing prices in British Columbia and Ontario. The Ontario prices do not include the 10-per-cent mark-up that the province pays pharmacists on top of the BAP for the wholesaling function. There is little or no justification for this mark-up with respect to lower-priced brands, which in Ontario are usually distributed directly from the manufacturer to the pharmacist. There may be more of a case with respect to some of the higher-priced brands. However, in both cases AAC prices are the same as BAPs, implying that the mark-up is nothing more than a windfall gain to pharmacists in Ontario.

The Product Incentive Plan — In October 1990 British Columbia introduced the product incentive plan (PIP). Its objectives are to reduce Pharmacare's drug costs by providing incentives for pharmacies to purchase and dispense drugs in a more cost efficient manner and to provide them with an additional source of revenue. In a news release dated 25 May 1990, the Ministry of Health, in announcing the PIP, said that it "will establish standard costs for major drug categories, and will reward pharmacists whose actual acquisition costs . . . are below the established standard costs."

To promote such cost savings, for each of the 239 product classes a product base price (PBP) was established equal to 10 per cent greater than the highest-priced brand in that group. In 102 instances there is one brand in the class, a single-source product, in the other 137 cases there are more than one, all interchangeable drugs.[28] When billing an amount lower than the PBP, the pharmacist receives 20 per cent of the difference between the PBP and the amount billed Pharmacare.

For single-source and interchangeable drugs, better buying practices on the part of the pharmacist – such as ordering larger lot-sizes or purchasing directly from the manufacturer – could result in a lower acquisition cost than the PBP reference standard. For interchangeable drugs, with 20 per cent of the difference between the PBP and the brand selected accruing to pharmacists, the PIP should provide an incentive for them to product select a lower-priced brand.

The PIP seems to have had a modest impact on overall Pharmacare drug costs. Pharmacare estimates that in the first 10 months after its introduction, PIP reduced total drug costs by 2.8 per cent. This estimate was derived from comparing projected costs – using historical volume growth patterns with a 4.5 per cent inflation factor – with actual drug costs, excluding PIP payments.

If the PIP payments are included, then the drug bill is 1.58 per cent higher than would otherwise be the case, reflecting the fact that the ratio of PIP payments to PIP savings was 1.56. Recalling the earlier discussion of equations 5.6

to 5.8, the savings due to incremental product selection as a result of the PIP do not appear to have been sufficient to offset the PIP payments for product selection that would have taken place in any event.

In order to take the analysis of the PIP a step further, we examined its impact on the same sample of drugs that were used in Table 5-8 for 1990-91 (Table 5-9). Prices for July-September 1990, the period immediately before the introduction of the PIP, are equal to unity. The bottom line of the table reports the mean values of the market and price data for the 14 drugs.

In 1990 and 1991 the market share of lower-priced brands increased from 40.6 per cent in the first half of 1990 to 48.4 per cent in March-April 1991, an increase of one quarter. There are a number of factors that might explain this trend. One is the autonomous increase over time in the market share of lower-priced brands.[29] This is reinforced by the increase in the number of lower-priced brands from an average of 2.5 per drug in the first half of 1990 to 3.4 in March-April 1991. The PIP could also be a factor, since the biggest jump in the market share of the lower-priced brands occurred in between July-September and October-December 1990. However, this is also when the biggest increase occurred in the number of lower-priced brands – from 2.5 to 3.0. Thus, while the increase in the market share of lower-priced brands could have been caused in part by the incentives provided by the PIP, they could also have been caused by other factors. More work is required to assess the quantitative impact of the PIP.

Table 5-9 also provides information on the mean price paid by Pharmacare for all brands of a given drug. On average, prices increased in the period leading up to the introduction of the PIP, declined by less than 1 per cent in the subsequent five months, and then returned to slightly above the level of the period immediately before the introduction of the PIP. These price movements reflect the increase in market share of lower-priced brands and the temporary drop in price for a small number of the higher-priced brands immediately following the introduction of the PIP.[30] The prices of all higher-priced brands were higher in March-April 1991 than in July-September 1990. The trend in the prices of lower-priced brands was much more varied, with about as many increases as decreases.

In sum, the PIP appears to have had a modest impact in percentage terms in the short run. Its impact was also modest in comparison with Nova Scotia's experience when it switched from an AAC system to a MAC system. There the market share of the lower-priced brands increased by 35 percentage points, and the mean price of interchangeable drug products fell by 20 per cent, all in the space of three months. It would appear that the PIP is unable to produce such results – at least over a comparable time period. Perhaps the incentive is too low, perhaps it is too complicated, perhaps there are hidden discounts which slow the transfer of market share that a MAC or BAP system is able to overcome, perhaps examined over a longer period the results will be more impressive.

The discussion of the various pricing systems in Ontario, British Columbia, and Nova Scotia makes it clear why the Pharmaceutical Manufacturers Association of Canada and its members prefer the AAC – they retain a large market share over which they can command a price premium. This applies particularly to drugs that have been introduced more recently and are likely to be higher priced. In contrast, under a BAP (or a MAC) system their market disappears as soon as a lower-priced interchangeable product appears in the formulary.[31] This, of course, also explains why generic drug manufacturers prefer the present BAP system in Ontario [Apotex 1988; Canadian Drug Manufacturers Association 1988; and Novopharm 1988].

Major Change: A Tendering System

An alternative to the BAP and AAC systems of setting drug prices and reimbursing pharmacists for high-volume interchangeable drugs is a tendering system. Qualified bidders would be invited to submit tenders to the provincial government purchasing agency. The lowest-priced tender would, other things being equal, be the winner. The tender could be for six months, the period selected by Saskatchewan under its standing-offer-contract system, or one year, as practised by some hospital buying groups.[32]

The advantages of a tender system are twofold. First, there is no incentive for the spread to exist. The drug firm gains market share by submitting low prices to the government purchasing agency, not by offering inducements to pharmacists to stock and sell their brand as opposed to a competing brand. Second, the competitive process inherent in tendering is likely to lead to low drug prices.

It is not at all clear, however, that tendering would result in lower drug prices than those in a well-managed and administered BAP or AAC system. It seems likely that there are constant returns to scale in the final dosage preparation stage of drug production – the major activity of drug firms in Canada. The raw material – at least for the lower-priced drug firms – is bought on the open market, while the amount of capital equipment does not seem to be great, especially for tablets and capsules. Thus prices in a competitive retail

Table 5-9

The impact of the product incentive plan[1] on drug prices and market shares of lower-priced brands, highest-dollar-volume interchangeable drugs,[2] B.C. Pharmacare, 1990-91

	Market share of lower-priced brands[3]					Average price, all brands[4]				
	Before PIP		After PIP			Before PIP		After PIP		
	January-June 1990	July-September 1990	October-December 1990	January-February 1991	March-April 1991	January-June 1990	July-September 1990	October-December 1990	January-February 1991	March-April 1991
	(Per cent)					(July-September 1990 = 1.0000)				
Drug, strength, and dosage form										
ranitidine HCl 150-mg tablet	67.0 (3)	71.0 (3)	75.0 (4)	75.9 (4)	78.1 (4)	0.9957	1.0000	0.9723	0.9620	0.9567
diltiazem HCl 60-mg tablet	15.0 (2)	19.0 (2)	24.0 (4)	28.0 (4)	29.5 (4)	0.9915	1.0000	0.9978	0.9907	0.9961
diltiazem HCl 30-mg tablet	17.0 (2)	22.0 (2)	27.0 (3)	31.1 (4)	33.1 (4)	0.9949	1.0000	0.9997	0.9940	0.9934
nifedipine 10-mg capsule	37.0 (2)	39.0 (2)	42.0 (2)	42.5 (3)	45.1 (3)	0.9797	1.0000	1.0035	1.0016	1.0097
glyburide 5-mg tablet	20.0 (1)	18.0 (2)	17.0 (2)	16.1 (2)	15.6 (2)	0.9569	1.0000	1.0166	1.0337	1.0883
triazolam 0.125-mg tablet	18.0 (3)	23.0 (3)	29.0 (4)	34.9 (4)	38.7 (4)	1.0051	1.0000	0.9854	0.9803	0.9898
atenolol 50-mg tablet	17.0 (1)	19.0 (1)	24.0 (1)	25.3 (2)	27.7 (3)	0.9807	1.0000	0.9864	0.9918	1.0090
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	47.0 (2)	48.0 (2)	51.0 (3)	52.4 (3)	53.9 (3)	0.9386	1.0000	1.0659	1.0749	1.0868
acetylsalicylic acid 650-mg ent. tablet	20.0 (4)	23.0 (4)	24.5 (3)	25.1 (3)	27.0 (3)	0.9921	1.0000	1.0020	0.9961	0.9684
furosemide 40-mg tablet										
timolol maleate 0.5% oph. sol.	71.0 (4) 9.0 (1)	71.5 (4) 10.0 (1)	74.0 (4) 11.0 (1)	74.7 (3) 11.4 (1)	75.9 (4) 12.4 (1)	0.9948 0.9799	1.0000 1.0000	0.9664 0.9884	0.9690 1.0171	0.9690 1.0418
naproxen 250-mg tablet	92.0 (3)	91.7 (3)	92.7 (4)	93.8 (4)	93.0 (4)	0.9847	1.0000	0.9853	0.9730	0.9785
cimetidine 300-mg tablet	81.0 (3)	81.0 (3)	83.0 (4)	82.4 (4)	84.1 (4)	0.9852	1.0000	0.9871	1.0006	0.9884
methyldopa 250-mg tablet	58.0 (4)	60.0 (3)	61.2 (3)	62.3 (4)	63.4 (4)	1.0040	1.0000	1.0069	1.0089	1.0208
Mean	40.6 (2.5)	42.6 (2.5)	45.4 (3.0)	46.9 (3.2)	48.4 (3.4)	0.9846	1.0000	0.9974	0.9996	1.0069

1 The plan was introduced in October 1990.
2 The highest-dollar-volume interchangeable drugs among the 32 highest-dollar-volume drugs paid for by the ODB in March 1989. Naproxen, cimetidine, and methyldopa were included because they were used in an earlier work comparing British Columbia and Ontario.
3 Market share measured in number of prescriptions. The numbers in parentheses are the number of lower-priced brands.
4 The price does not include the product incentive plan payment.
Source Based on data supplied by B.C. Pharmacare; and Gorecki [1986c, 108, Table 5].

market, especially one as large as Ontario, should not be that different from a tendering system.

The major advantage of a tendering system is that the incentive for the spread is removed. The introduction of the BAP in 1986 appears to have substantially reduced the spread in Ontario – at least judged by the fact that the Saskatchewan and BAP prices are now very similar. The exception is those instances where there were a fighting brand, a name brand, and a generic brand – an increasingly important group of drugs. However, Ontario has reduced the spread on some of these drug prices as well.

A tendering system has some disadvantages. First, the purchasing agency may estimate the quantity required for the designated period incorrectly, which would lead to surpluses or shortages. Second, if the winning bidder changes every six months or so, patient/consumers have to change brands, which could be a cause for concern. This may account in part for the importance of no-substitution prescriptions for the higher-priced brands in Saskatchewan. Third, unlike Saskatchewan or hospital buying groups, the ODB only purchases drugs for a portion of the Ontario population, so a tendering system could disrupt the marketplace unless arrangements were worked out with the other providers.

The arguments do not seem to be overwhelmingly in favour of a tendering system for the ODB as a way for purchasing high-volume interchangeable drugs. It would involve substantial change, and that not that long after the introduction of the BAP system. Nevertheless, this does not preclude experimenting with such a system for some interchangeable drugs, particularly those drugs where a generic brand, a fighting brand, and a brand name are present. Then, if the spread continued despite the introduction of the market assessed price, there would be a body of knowledge and experience to draw upon should this option be adopted.

Major Change: Mandating Prices

All the pricing or reimbursement systems for interchangeable drugs discussed so far are based on the competitive market. In principle, competitive markets drive prices down to the level where the firm earns no more than a competitive rate of return, with an allowance for risk. However, the Pharmaceutical Inquiry of Ontario takes the view that these market mechanisms do not function as well as they should and suggests mandating certain pricing rules.

According to the Pharmaceutical Inquiry of Ontario, the return to the firm that produces the first interchangeable brand in the formulary is too great. It says: "Since costs and marketing expenses of generic products are relatively low, and the market can be sizeable, the Committee feels that recent initial generic prices have been unnecessarily high" [1990*a*, 64]. It recommends that the first interchangeable brand be listed at 60 per cent of the brand-name product's price as it appears in the formulary immediately prior to the one in which the lower-priced brand appears. The 60 per cent is based upon the fact that when there is only one lower-priced interchangeable brand, its price is between 75 and 85 per cent that of the brand-name price, and when there are two lower-priced interchangeable brands, the lowest BAP is 40 to 60 per cent of the brand-name price.

There are at least two difficulties with this. First, an important function of the marketplace is to provide incentives for the introduction of cheaper products of the same or better quality than those currently on the market. These incentives usually consist of a period when the firm responsible for the change enjoys a return on its efforts. In the case of lower-priced interchangeable drug products, there is a race between the small number of firms to be first to have their brand listed in the formulary as interchangeable. The period of exclusivity therefore lasts at least six months – the length of time between formularies – and maybe longer. Any attempt to reduce the incentive for the lower-priced entrant to be first may result in a reduction in the rate of introduction of lower-priced interchangeable products.

The inquiry does not present evidence that the return to being first is, in fact, too high. There do not appear to be substantial barriers to entry, and new firms continue to enter the market. In addition, brand-name firms increased price competition by introducing fighting brands. Furthermore, evidence indicates that the rates of return of generic firms, measured in a number of ways, are below those of the brand-name companies.[33]

In order to quantify the length of time that the first lower-priced interchangeable brand monopolizes the lower-priced segment of the market, Table 5-10 presents the dates that the first two brands to enter this segment were listed in the formulary and the resulting lags. There is a considerable variance in the lags, from none – in the case of nifedipine 10-mg capsules, captopril 25-mg and 50-mg tablets, and lorazepam 1-mg tablets – to at least 16 years for the two acetylsalicylic acid dosage strengths.

The Pharmaceutical Inquiry of Ontario study refers to drugs introduced more recently, for which the lag tends to be shorter [1990*a*]. The longest lags were for acetaminophen compound with codeine and acetylsalicylic acid, much older drugs, where there may be much less incentive

Table 5-10

Lag between the formulary listing of the first and second lower-priced interchangeable brands of the highest-dollar-volume interchangeable drugs,[1] Ontario Drug Benefit, 1975-91[2]

	Date of listing		
	First	Second	Lag
			(Years)
Drug, strength, and dosage form			
ranitidine HCl 150-mg tablet	July 1987	January 1990	2.5
diltiazem HCl 60-mg tablet	January 1989	July 1990	1.5
captopril 25-mg tablet	February 1991	February 1991	0.0
salbutamol inh. 200-dose package	July 1989	July 1990	1.0
diltiazem HCl 30-mg tablet	January 1989	July 1990	1.5
diclofenac sodium 50-mg ent. tablet	January 1990	February 1991	1.0
nifedipine 10-mg capsule	July 1988	July 1988	0.0
glyburide 5-mg tablet	February 1991	. . .	. . .
triazolam 0.25-mg tablet	January 1989	July 1989	0.5
amiloride HCl and hydrochlorothiazide 5-mg and 50-mg tablet	January 1990	February 1991	1.0
atenolol 50-mg capsule	January 1989	February 1991	2.0
acetaminophen compound with codeine 30-mg tablet	August 1975	December 1986	11.5
verapamil HCl 80-mg tablet	July 1990	February 1991	0.5
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	January 1982	January 1985	3.0
captopril 50-mg tablet	February 1991	February 1991	0.0
acetylsalicylic acid 650-mg ent. tablet	January 1975	. . .	. . .
furosemide 40-mg tablet	August 1975	July 1976	1.0
timolol maleate 0.5% oph. sol.	July 1988	. . .	. . .
acetylsalicylic acid 325-mg ent. tablet	January 1975	. . .	. . .
acetaminophen compound with codeine 15-mg tablet	August 1975	July 1987	12.0
psyllium mucilloid oral pd. 340-g package	July 1977	January 1979	1.5
lorazepam 1-mg tablet	December 1986	December 1986	0.0

1 The highest-dollar-volume interchangeable drugs among the 32 highest-dollar-volume drugs paid for by the ODB in March 1989.
2 To February 1991 formulary.
Source: Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989; and Ontario Ministry of Health, *Drug Benefit Formulary/Comparative Drug Index*.

to enter. In other words, for more recently introduced higher-dollar-volume drugs which are likely to be of most concern, the lag tends to be shorter. This lag is likely to shrink further in the future, since an increasing number of fighting brands appear to be entering the formulary just before or at the same time as the generic brands. The protection for seven to ten years before a compulsory licence can be issued that is afforded under recent amendments to the Patent Act should leave ample time for several generic brands to be ready to enter the formulary simultaneously.

The second problem with the inquiry's recommendation is that it assumes that there will be no reaction by the owner of the brand-name product. If a firm anticipates the entry of a lower-priced interchangeable product, it might decide to lower its price by, say, 20 per cent in the formulary immediately before the lower-priced brand enters. This would force the entrant to charge a much lower price than would otherwise be the case, so much lower that entry does not take place.

Nevertheless, in making this recommendation, the inquiry has highlighted two areas of the reimbursement system that do require consideration. The first is the criteria used in deciding whether to list a product in the formulary and the way in which the ODB, as a very large purchaser of drugs, uses its buying power. This is discussed in Chapter 7. The second is the reaction of brand-name firms to competition from lower-priced interchangeable brands, which is examined in Chapter 6.

In conclusion, in terms of average prices charged for interchangeable products, the ODB seems to do as well as, if not better, than the alternatives discussed. The only noticeable exception was in the comparison between Ontario and Saskatchewan in situations where there were a fighting

brand, a generic brand, and a brand-name product present. This does not mean that the current reimbursement system cannot be improved. The incentives for a spread remain and are unlikely to disappear. In view of this, the market-assessed price, combined with price monitoring and a single formulary price should be given serious consideration. Because it carefully utilizes the competitive pressures of the marketplace, this option could reduce the price-spread.

6 There Is More than One Way to Skin a Cat: Brand-Name Firm Marketing Strategies

The large multinational drug firms that dominate the pharmaceutical industry, both in Canada and abroad, are the firms that market the higher-priced brand-name products that lose market share because of interchangeability. These firms frequently rely on a small number of high-dollar-volume drugs for a large portion of their sales and profits [e.g., see Commission of Inquiry on the Pharmaceutical Industry 1985, Table A42, 166-83; Gorecki 1986*a*, footnote 15, 375]. It is these high-dollar-volume products – winners – that the generic drug manufacturers typically target. Winners require considerable time and resources to discover, develop, and market [e.g., see Di Masi et al. 1991]. Brand-name firms do not usually have a ready supply of these products to offset the effect of generic competition.

Brand-name manufacturers thus have an incentive to design strategies to retain market share, preferably at the higher price charged before the entry of the generic brand. If these strategies are successful, increased drug costs and misallocated resources could be the result; public and private interests may not coincide. It therefore behooves policymakers to carefully evaluate brand-name manufacturers' strategies and, where appropriate, take steps to ensure the integrity of their programs.

In this chapter we examine the three most important marketing strategies that many brand-name manufacturers have followed in order to retain market share: promoting brand loyalty, introducing fighting brands, and shifting demand away from interchangeable dosage forms and strengths.[1] Not all of these strategies can be considered under the rubric of marketing. In the mid-1980s, brand-name firms successfully pushed for legislation to partially restore the patent protection for drugs that compulsory licensing, introduced in 1969, had done so much to attenuate. Under the new arrangements, brand-name firms are given a seven-to-ten-year period of exclusivity, providing, of course, that the patent is still valid. Before the legislation, the lag between the brand-name firm marketing the drug and the licensee's brand appearing had been as short as four years [Gorecki 1986*c*, Table 5; see also Hoffman-LaRoche 1984, 8-9]. Thus the period in which brand-name firms do not experience competition from generic firms on newly introduced products is now longer. As a result, in the short-to-medium term, drug bills will be higher because of the reduced flow of generic brands for high-dollar-volume drugs.

Promoting Brand Loyalty: No-Substitution Prescriptions

Promoting brand loyalty among health professionals, and to a lesser extent patient/consumers, has long been employed by brand-name manufacturers. This strategy can be pursued through the media (especially print), by detail persons (sales representatives who visit individual physicians and pharmacists), and in the courts. It has the potential for a high payoff at what is probably the lowest outlay of the three strategies considered here.

Brand-name firms use a number of arguments to establish and retain brand loyalty.[2] For example, they argue that there are differences between the nonactive ingredients of the generic and the brand-name drug product, and despite the fact that they have been declared interchangeable by provincial governments, physicians should pause before allowing a generic brand to be used. They also argue that they undertake the research that leads to new drugs, and that they therefore deserve a fair return on their innovative efforts. In addition, they have attempted (unsuccessfully) to prevent generic firms – through the courts – from using the same tablet or capsule size, shape, and colour as the brand name.[3]

The Importance and Cost of No-Substitution Prescriptions

Physicians can express their loyalty to a brand-name product by writing, in their own hand, the words "no substitution" on the prescription. In some provinces they are also required to undertake some additional paperwork. Under the Ontario Drug Benefit (ODB) program this is completing a PC-34 form.[4] The ODB will then reimburse the pharmacist at the brand-name product's best available price (BAP). However, pharmacists do not receive the 10-per-cent mark-up on no-substitution prescriptions.

The no-substitution rate varies considerably by province. In the mid-to-late 1980s, for example, it ranged from highs of 25 per cent in New Brunswick and 15 per cent in Saskatchewan, to lows in the 1-to-2-per-cent range in Manitoba and Ontario [New Brunswick Commission on Selected Health Care Programs 1989, 73]. High no-substitution rates are likely

to increase program costs substantially. In 1985/86, for example, no-substitution prescriptions increased average drug material cost per person in Saskatchewan from $50.71 to $58.69, or by 15.7 per cent [Saskatchewan Review Committee to the Minister of Health 1989, 51]. But even where the overall no-substitution rate is low, it may still be high for individual interchangeable drugs.

Although no-substitution rates are low in Ontario, they have been increasing since 1981/82, with a particularly large increase between 1986/87 and 1987/88 (Table 6-1). In 1988/89 the ODB paid $15 million for no-substitution prescriptions.[5]

In order to examine the incidence, cost, and importance of no-substitution prescriptions, we excluded single-source and noninterchangeable drugs and examined the market share of no-substitution prescriptions for 17 interchangeable drugs among the 32 highest ODB sellers in March 1989 (Table 6-2). Two estimates of the cost to the ODB in that year are presented. Column B is the incremental cost of a no-substitution prescription to the ODB per tablet or capsule – the difference between the lowest BAP and the brand name BAP. In column A the same calculation is presented, except 10 per cent is added to the lowest BAP, so it represents the actual price paid by the ODB for lower-priced brands.

On average, no-substitution prescriptions are of little importance among the leading interchangeable drugs, accounting for less than 4 per cent of the market. Nevertheless, this low overall rate conceals a substantial variation, from less than 0.5 per cent to 16 per cent. When all the interchangeable brands of a drug are sold by brand-name firms (drugs like glyburide, triazolam, and beclomethasone dipropionate), and where the drug has been on the market for some time (e.g., acetaminophen compound with codeine), rates are more likely to be low. Recently introduced drugs where there is some generic competition – such as ranitidine HCl 150-mg tablets, diltiazem HCl 30-mg and 60-mg tablets, nifedipine 10-mg capsules, atenolol 50-mg capsules, and timolol maleate 0.5 per cent ophthalmic solution – are more likely to have higher no-substitution rates. An exception to this somewhat rough and ready generalization is psyllium mucilloid, whose no-substitution rate is twice that of any other interchangeable product. It may be that the brand name for this over-the-counter drug, Metamucil, is frequently requested by patient/consumers when visiting the physician, based on brand-name recognition because of advertising.

No-substitution prescriptions cost the ODB between $77 thousand and $100 thousand per interchangeable drug product in 1989. The overall cost for the sample of drugs in Table 6-2 was at least $1.25 million. Again, there is substantial variation, with a small number of drugs accounting for a very large percentage of the cost. The cost of no-substitution prescriptions on ranitidine HCl 150-mg tablets was one third of the total; when combined with psyllium mucilloid oral powder 340-g packages it was two thirds of the total.[6]

Where the cost of no-substitution prescriptions is low, this could reflect the small difference between the lowest BAP and the BAP for the no-substitution brand. Indeed, where the difference is less than 10 per cent, no-substitution prescriptions actually reduce ODB drug costs, at least according to estimate A. However, only two drugs fall into this category. For glyburide 5-mg tablets the saving was $324, and for beclomethasone dipropionate aerosol powder 200-dose packages the saving was even less. In both of these cases the interchangeable brands were brand names.

Table 6-1

Number of no-substitution claims under the Ontario Drug Benefit, 1981-89[1]

	Number	Proportion of all claims
		(Per cent)
1981/82	42,318	0.2
1982/83	60,350	0.3
1983/84	105,373	0.4
1984/85	137,455	0.5
1985/86	221,968	0.7
1986/87	239,914	0.7
1987/88	443,898	1.3
1988/89	472,849	1.3

1 Fiscal year ending March 31.
Source Ontario Ministry of Health, "Managing by results, results abstracts."

No-Substitution Prescriptions: A Formal Analysis

The proportion of all drug claims (or dollar volume) that is accounted for by no-substitution prescriptions can be written as follows:

$$NS = \beta \frac{ID}{ID + SS + NI} \qquad (6.1)$$

Table 6-2

The importance of no-substitution prescriptions among the highest-dollar-volume interchangeable drugs,[1] Ontario Drug Benefit, 1989

	No-substitution prescriptions		
	As a proportion of total quantity[2]	Cost[3]	
		A[4]	B[5]
	(Per cent)	(Dollars)	
Drug, strength, and dosage form			
ranitidine HCl 150-mg tablet	8.5	437,592	647,308
diltiazem HCl 60-mg tablet	4.2	58,910	107,170
diltiazem HCl 30-mg tablet	3.2	28,112	51,197
nifedipine 10-mg capsule	6.8	136,844	176,066
glyburide 5-mg tablet	0.1	–324	56
triazolam 0.25-mg tablet	1.1	1,449	4,886
atenolol 50-mg capsule	5.4	35,373	56,003
acetaminophen compound with codeine 30-mg tablet	0.2	1,581	1,822
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	3.9	95,338	99,387
acetylsalicylic acid 650-mg ent. tablet	2.9	504	3,526
furosemide 40-mg tablet	1.3	31,265	31,655
timolol maleate 0.5% oph. sol.	7.5	51,699	72,596
acetylsalicylic acid 325-mg ent. tablet	1.7	4,245	5,064
acetaminophen compound with codeine 15-mg tablet	0.1	219	286
psyllium mucilloid oral pd. 340-g package[6]	15.8	421,908	421,908
beclomethasone dipropionate aero. pd. 200-dose package	0.006	–9	3
lorazepam 1-mg tablet	2.6	8,358	10,921
Mean	3.8	77,239	99,403

1 The 32 highest-dollar-volume drugs paid for by the ODB in March 1989.
2 Includes all no-substitution prescriptions for brands with a BAP greater than the lowest BAP.
3 Estimates for calendar year 1989 based on the figure for March.
4 Estimate A: [(no sub., BAP – (1.10 • low, BAP))] • No sub., *Q.* • 12. Where: no sub., BAP = the March 1989 BAP for the no-substitution brand; low, BAP = the lowest March 1989 BAP of the interchangeable brands; no-sub., *Q* = the quantity of the drug for which no-substitution prescriptions are written.
5 Estimate B: (no sub., BAP – low, BAP) • No sub., *Q.* • 12.
6 For over-the-counter drugs, A and B are the same, since there appears to be no 10-per-cent mark-up.
Source Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989; and Ontario Ministry of Health [1989a].

where

β = the proportion of all interchangeable drug claims (or dollar volume) accounted for by no-substitution prescriptions;
ID = the number of claims (or dollar volume) of interchangeable drugs;
SS = the number of claims (or dollar volume) of single-source drugs; and
NI = the number of claims (or dollar volume) of noninterchangeable drugs.

The term β will vary between 1 (all interchangeable claims are no-substitution prescriptions) and 0 (there are no claims which are no-substitution prescriptions). The denominator of *NS* is just the total number of claims (or dollar volume) paid by the ODB per period of time.

There are a number of possible reasons why *NS* could increase over time. These include:

- Physicians decide, other things being equal, to write more no-substitution prescriptions. In this case β would increase.

- The relative importance of drugs designated as interchangeable increases, other things being equal. In this case *ID* increases at a faster rate than *SS* and *NI*. This could occur for at least two reasons: first, more drugs are designated as interchangeable in the formulary, and, second, the relative importance of those drugs already designated as interchangeable increases.

- There is a rise in both β and the relative importance of *ID*. This could occur, for example, if a number of new

drugs were listed as interchangeable and no-substitution prescriptions for these drugs were higher than normal until physicians became familiar with the newly listed brand.

In the period 1981-88, the overall importance of interchangeable drugs for the ODB declined (Table 7-1). This suggests that the rise in *NS* is due to an increase in β.

In order to investigate further the dramatic change in the number of no-substitution claims, we examined those 30 drugs in March 1987 and those 32 drugs in March 1989 that accounted for approximately one third of ODB expenditure. These dates were selected because they are just before and just after the big increase in no-substitution prescriptions (see Table 6-1). For each drug we examined all claims for a particular dosage form and strength rather than all dosage forms and strengths of a given drug.

Using the arguments in equation 6.1, various ratios are presented in Table 6-3. The results, measured in dollar volume rather than number of claims, show a dramatic increase in the dollar volume accounted for by interchangeable drugs, from 22.4 per cent to 56.2 per cent. This reflected in the increase in the number of drugs that were classified as interchangeable, from 10 out of 30 in 1987 to 17 out of 32 in 1989. If the only change that occurred between 1987 and 1989 was the increase in the dollar volume of interchangeable drugs, then *NS* would have increased from 0.71 to 1.77 per cent. The value of β increased between 1987 and 1989 from 3.15 per cent to 5.69 per cent. If the only change that occurred between 1987 and 1989 was the increase in the proportion of the dollar expenditure on interchangeable drugs accounted for by no-substitution claims, then *NS* would have risen from 0.71 to 1.27.

Thus it appears that the most important cause of the increase in no-substitution claims was the fact that some leading high-volume drugs, such as ranitidine HCl 150-mg tablets, diltiazem HCl 30-mg and 60-mg tablets, nifedipine 10-mg capsules, triazolam 0.25-mg tablets, atenolol 50-mg tablets, and timolol maleate 0.5 per cent ophthalmic solution became interchangeable, rather than an increase in the incidence of no-substitution claims on a given set of drugs. The rise in β from 3.15 to 5.69 per cent may thus be seen as having been temporary, as physicians and patients got used to the newly listed interchangeable brands.

However, this is only part of the story. If it is correct, one would expect drugs that were interchangeable in both 1987 and 1989 to have lower no-substitution rates than drugs made interchangeable more recently, and the trend in no-substitution prescriptions for this group to either be stable or declining. In Table 6-4, the interchangeable drugs from the sample in Table 6-3 for which ODB expenditure accounted for by no-substitution claims was at least 4 per cent in March 1987 or March 1989 are used to estimate the significance of no-substitution claims. For the three drugs for which data are presented in the table for both 1987 and 1989 the importance of no-substitution claims increased, dramatically in the case of psyllium mucilloid oral powder 340-g package. This is despite the fact that all three had been interchangeable since at least February 1984. This suggests that the importance of no-substitution claims for new interchangeable drugs will not necessarily fall. It would appear that more general factors are responsible for the increase in no-substitution prescriptions. One of these might be the campaign by brand-name firms to promote brand loyalty.

Table 6-3

The importance of various factors[1] in accounting for the changing level of no-substitution claims for the highest-dollar-volume drugs,[2] Ontario Drug Benefit, March 1987-89

			Number of drugs	
	1987	1989	1987	1989
	(Per cent)			
ID/(*ID* + *SS* + *NI*)	22.4	56.2	10	17
SS/(*ID* + *SS* + *NI*)	72.1	41.0	18	14
NI/(*ID* + *SS* + *NI*)	5.5	2.8	2	1
β	3.1	5.7	...	...
NS	0.7	3.2	...	...

1 These are derived from equation 6.1. *NS*, *ID*, *SS*, and *NI* are measured in dollars. See text. Very few no-substitution claims for *NI* and *SS* are omitted.

2 The highest dollar volume, by dosage form and strength, accounting for 34.6 per cent of all ODB expenditure on drugs in 1987, and 34.5 per cent in 1989, including the dispensing fee.

Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1987 and 1989.

Assessment

There is considerable variation among provinces and drugs in no-substitution prescriptions, and much study is required in order to fully understand the determinants of these variations, particularly the role played by the brand-name drug firms in promoting brand loyalty. Nonetheless, some observations are possible.

The New Brunswick Commission on Selected Health Care Programs suggested that in New Brunswick the reason for the low use of generic drugs, and by implication the cause of the high no-substitution rate, was that: "Physicians

Table 6-4

No-substitution claims among the highest-dollar-volume interchangeable drugs[1] for which those claims exceeded 4 per cent of ODB expenditure on the drug, March 1987 and 1989[2]

	No-substitution claims as a proportion of			
	Dollar volume	Claims volume	Dollar volume	Claims volume
	1987		1989	
	(Per cent)			
Drug, strength, and dosage form				
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	2.9	2.3	5.1	3.6
psyllium mucilloid oral pd. 340-g package	12.2	6.2	22.1	12.0
cimetidine 300-mg tablet	10.8	4.7	15.7	6.3
ranitidine HCl 150-mg tablet	...	...	9.9	8.3
diltiazem HCl 60-mg tablet	...	...	4.7	4.1
nifedipine 10-mg tablet	...	...	8.5	6.3
atenolol 50-mg tablet	...	...	6.2	5.5
timolol maleate 0.5% oph. sol.	...	...	8.6	6.9

1 For definition of the sample, see Table 6-3.
2 In either year.
Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1987 and 1989.

and the public are not well informed on the safety or interchangeability of generic products. This is a serious obstacle to achieving greater use of these products, and hence cost containment" [1989, 74]. Under these conditions of prescriber and patient/consumer ignorance, it is likely to be much easier for the brand-name manufacturer to retain brand loyalty.

There was a similar situation in Ontario in the late 1960s and early 1970s (see Chapter 3). The government's response was to undertake an extensive set of well-thought-out policies to promote acceptance of interchangeability among health professionals. As a result, attempts by brand-name manufacturers to promote brand loyalty by encouraging physicians to write no-substitution prescriptions have met with little success.

In many respects Saskatchewan is similar to Ontario in that product selection is permissive, a formulary is published that includes interchangeable drug products, and strong incentives exist for the product selection of lower-priced brands. Yet, as successive reports and inquiries have noted, there is a high rate of no-substitution prescriptions [e.g., Saskatchewan Commission on Directions in Health Care 1990, 143-44]. The two areas where Saskatchewan differs from Ontario may partly explain the difference in their rates of no-substitution prescriptions. In Ontario physicians are required to complete a PC-34 form, while in Saskatchewan all that is required is for the physician to write "no substitution" on the prescription. Also, in Saskatchewan the generic brand usually wins the standard offer contract, with the result that the brand-name firm can only retain market share with no-substitution prescriptions.

Policy Options

In Chapter 7 we examine the issue of no-substitution prescriptions in the context of the approval process for interchangeable drugs. We conclude that there are few justifications for no-substitution subscriptions. In view of this, the following policy options could be considered:

- Abolish no-substitution prescriptions, except where the physician can provide clinical justification for them.

- Charge patient/consumers who prefer the brand-name product either the whole cost of the prescription (the dispensing fee and the drug cost) or the difference between the lowest-priced interchangeable brand and the brand preferred.

- Provide counter-advertising and information to patient/consumers and physicians about interchangeability.

These measures would essentially raise the cost of no-substitution prescriptions to consumer/patients and/or

physicians, while at the same time providing reassurance as to the quality of interchangeable brands. There is some evidence that they would reduce, perhaps dramatically, the importance of no-substitution prescriptions. This occurred in Saskatchewan after a patient/consumer copayment on the cost of a prescription was introduced (see Chapter 5). In New Brunswick the no-substitution rate fell from 25 per cent in the late 1980s to 3 per cent in 1991, the year after it introduced policies similar to the options outlined above.[7] Newfoundland's no-substitution rate for those on social assistance fell from 8 per cent to virtually zero in 1991 after the government introduced a policy whereby it would pay no more than the lowest cost of the lowest-priced brand, unless the physician could justify a higher-priced brand.[8] In sum, it would appear that ultimately brand loyalty is not very strong.[9]

Pricing Strategies

The second response by brand-name manufacturers to generic competition has been the introduction of low-priced brands designed to compete on a price basis with generics. According to the Pharmaceutical Manufacturers Association of Canada, brand-name firms have adopted two pricing strategies in the face of competition from lower-priced generic brands:

> One strategy that appears to have been used is where the innovator [i.e., a brand-name firm] attempts to retain sales and prescription share of the market by being price competitive; the other strategy, perhaps that most commonly used, is for the innovator to hold the line on price, which serves to retain margins at the expense of unit volume [1984*a*, 51].

Brand-name drug firms faced a dilemma: there were two market segments for an interchangeable drug, but they only had one brand to serve both segments. In the first market segment the brand-name firm could command a price premium over the generic brand, due to either brand loyalty or inertia on the part of physicians. In the second market segment the criteria for brand choice was price. This market segment was created largely as a result of compulsory patent licensing of drugs, the expiry of patents on existing drugs, and provincial price and product selection rules that encouraged or compelled the dispensing of lower-priced interchangeable brands. Under some systems, such as Ontario's or Saskatchewan's, the price-sensitive segment was quite large, while in others, such as British Columbia's and Nova Scotia's, it was smaller.

There were good reasons for brand-name firms to favour a high-price strategy. They might not be able to prevent the leakage of their brands between markets in Canada if they charged low prices in some Canadian markets but not in others. Even if the drugs could not be transported between markets, other countries could look at the brand-name prices in the Ontario, Quebec, or Saskatchewan formularies to determine whether they were being charged appropriate prices [United States Senate, Special Committee on Aging 1991; United States Department of Health and Human Services 1991].[10]

There is also evidence that a low-price strategy was a failure.[11] Hoffman-LaRoche gave away Valium to hospitals between June 1970 and June 1971, but the generic competition captured much of this market once the company charged a positive price, and Hoffman-LaRoche was convicted of predatory pricing under Canada's competition law [Gorecki 1986*b*].

For much of the 1970s the high-price strategy seemed the most sensible alternative for brand-name firms to follow. However, a number of changes occurred that required the brand-name firms to reconsider their pricing strategy. First, the relative importance of the high-priced and low-priced market segments changed, as more and more provinces introduced price and product selection rules or strengthened existing ones to provide greater incentives for the dispensing of lower-priced interchangeable brands. Quebec, for example, made a decisive shift in this direction in the early 1980s [Gorecki 1986*c*, 1987*a*]. Second, as generic firms grew larger and more efficient, the prospect arose that the period in which the brand could expect to command a monopoly at the high price would be reduced, as the lag between the marketing of the brand name and generic brands narrowed.[12]

Fighting Brands

The pricing strategy that brand-name firms adopted in the face of these changes was to introduce an additional brand designed to compete with the generic brands. Essentially, recognizing that there was a high- and a low-priced market segment for interchangeable drugs, they in effect price-discriminated. Many of the problems with the low-price strategy for the brand name would not apply to the brand designed specifically to meet competition in the lower-priced segment of the market.

The idea of introducing a separate lower-priced brand was not new. Hoffman-LaRoche considered it as early as 1974 [Gorecki 1986*b*, 172-73]. It was only in the mid-1980s, however, that two brand-name firms turned the idea into reality. The growing strength of the generic brands may have been the decisive factor. One of the two firms, the

Upjohn Company of Canada, justified its strategy in the following terms:

> After reviewing the largely unsuccessful strategies of other ethical pharmaceutical companies to offset the impact of generics, Upjohn decided to create a new company, Kenral Inc. Kenral was established to market Upjohn products for which compulsory licenses have been or may be issued. The strategy is one of survival [1984, 3].

A Brief History of Fighting Brands

In this study the lower-priced brands that were developed to compete with lower-priced generic drugs are referred to as fighting brands. Other terms have been used, such as "pseudo-generics" and "Ultragenerics."[13] Fighting brands first appeared in the Ontario formulary when Kenral entered in February 1984 with its fighting brand of Upjohn's ibuprofen. Syncare – a division of Syntex – appeared with its fighting brand of Syntex's naproxen in the July 1984 formulary. Then more than four years elapsed before Rhodiapharm, a subsidiary of Rhone Poulenc Pharma, entered in the January 1989 formulary with its fighting brands of Rhone Poulenc's ketoprofen and trimipramine.[14]

At first, all three of these firms that specialized in marketing fighting brands confined their efforts to drugs for which their parent marketed the brand-name product. Then Kenral and Syncare started marketing fighting brands for other firms. Kenral introduced Pharmacia (Canada)'s fighting brand of sulfasalazine and Allergan Pharmaceuticals' fighting brand of chloramphenicol in the April 1987 formulary, and Syncare introduced Sandoz Canada's fighting brand of pindolol in the July 1989 formulary.

The stock of fighting brands has been steadily increasing since 1984, especially in 1989 and 1990 (Table 6-5).[15] In the first half of 1991, Kenral, Syncare, and Rhodiapharm were the only firms with fighting brands listed in the Ontario formulary. Together they had fighting brands covering 20 drugs. Kenral, the most important, marketed the fighting brands of 13 drugs for six brand-name firms, including its parent. Syncare marketed fighting brands of five drugs for five firms. All these fighting brands had at least one low-priced competitor by February 1991.

Generally the firms marketing the fighting brands do not manufacture the drugs they sell; they are manufactured either by their parent or another firm.[16] The manufacturers supply the necessary documentation required for the fighting brand to gain regulatory approval at the federal and provincial levels. Various types of business arrangements can be made between the brand-name firm and the fighting-brand firm; for example, when Kenral markets a fighting brand for a firm that is not its parent, it is paid a commission on its sales. The brand-name firm sets a base price below which Kenral must not go.

The fighting brands contain the same ingredients as the brand name, a fact that is sometimes used in advertising them. Syncare, for example, uses such advertising for its Ultragenerics trademark. The fighting brand may, however, have a different physical appearance from the brand name; for example, the imprimatur stamped on the pill, its shape, or its colour may be different.

How Important Are Fighting Brands?

The number of brands and the market shares of brand-name drugs, fighting brands, and generic brands for the 32 drugs that had the highest dollar volume in March 1989, for the period 1989-91, are presented in Table 6-6. During the first six months of 1989, of the leading 17 drugs considered interchangeable in the Ontario formulary, a fighting brand was present in only one instance – triazolam 0.25-mg tablets. In this particular case the fighting brand was launched before the generic brand and captured 82.3 per cent of the market.

The number of fighting brands had increased considerably by the first half of 1991. Of the 32 drugs, 23 were interchangeable, and there were fighting brands for eight of the drugs, all competing with at least one generic brand. In three instances there were three generic competitors. The fighting brands are not distributed equally among the leading interchangeable drugs, but heavily concentrated among the highest sellers. Of the 10 highest-dollar-volume interchangeable drugs, fighting brands were present for six in 1991, but for the next 10 highest only two have fighting brands. It seems that generic drug manufacturers rely on breaking into these high-dollar markets for a large portion of their profits, and that fighting brands have the potential to considerably reduce their returns.

Fighting-Brand Pricing and Entry Policies

In marketing the fighting brand, the firm has to decide whether to enter the market before, at the same time as, or after the generic brand – and whether to meet or beat the generic's price. The advantage of entering the market before the generic is that the low-price segment of the market is pre-empted. The generic firm will thus have to wait longer to gain market share and may have to charge a lower price than would otherwise be the case in order to take the market away from the fighting brand. Thus the generic firm's costs

Table 6-5

Price ratios and competitors of fighting brands, and date fighting brand was first listed in Ontario formulary, 1984-91

Drug, strength, and dosage form[5]	Date fighting brand first entered formulary	Number of generic-firm brands[1]: Prior to entry[2]	Number of generic-firm brands[1]: On entry[3]	Ratio of fighting brand's BAP to that of: Lowest generic brand	Ratio of fighting brand's BAP to that of: Brand name[4]
ibuprofen 400-mg tablet (KNR)[6]	February 1984	0	2	1.0376	0.8500
naproxen 250-mg tablet (SYN)	July 1984	2	2	0.9155	0.5519
prednisone 5-mg tablet (KNR)	July 1984	4	4	0.6766	0.8494
erythromycin base 250-mg tablet (KNR)	December 1986	1	1	0.9449	0.9330
sulfasalazine 500-mg ent. tablet (KNR)*	April 1987	1	2	0.7566	0.6121
chloramphenicol 0.5% oph. sol. (KNR)*	April 1987	1	1	1.3889	0.7987
sulfacetamide sodium 10% oph. sol. (KNR)*	April 1987	2	2	1.5736	0.6704
prednisolone acetate 1% oph. sol. (KNR)*	April 1987	0	0	...	0.8258
haloperidol 5-mg tablet (KNR)*	January 1988	1	2	1.0000	0.4558
trimipramine 25-mg tablet (RHD)	January 1989	1	1	1.3779	0.9992
triazolam 0.25-mg tablet (KNR)	January 1989	0	0	...	0.8755
pindolol 5-mg tablet (SYN)*	July 1989	1	1	1.0499	0.7647
nadolol 80-mg tablet (SYN)*	January 1990	1	1	1.0476	0.7966
salbutamol inh. 200-dose package (KNR)*	July 1990	1	1	0.9524	0.7124
verapamil 80-mg tablet (KNR)*	July 1990	0	0	...	0.9500
alprazolam 0.25-mg tablet (KNR)	July 1990	0	0	...	0.9496
ranitidine HCl 150-mg tablet (KNR)*	July 1990	2	2	0.9550	0.7276
ketoprofen 50-mg capsule (RHD)	July 1990	1	1	0.9126	0.6499
diltiazem HCl 60-mg tablet (SYN)*	February 1991	2	3	1.0500	0.7993
captopril 25-mg tablet (SYN)*	February 1991	0	1	1.2800	0.9600

*The firm marketing the fighting brand is *not* owned by the manufacturer of the brand name.

1 A number of drugs manufactured by firms not usually thought of as generic were included: erythromycin base 250-mg tablet, Abbott Laboratories; chloramphenicol 0.5% oph. sol., Parke-Davis; and sulfacetamide sodium 10% oph. sol., Schering Canada. They were included because they appeared to be competing on a price basis.

2 Listed in the formulary before the one in which the fighting brand first appeared.

3 The number of generic brands listed in the formulary when the fighting brand enters.

4 In all cases except erythromycin base 250-mg tablet and prednisone 5-mg tablet the brand name has the highest BAP.

5 On some occasions there was more than one strength listed. The strength with the highest dollar volume of ODB claims in March 1989 was used.

6 Letters in parentheses are the companies that marketed the fighting brand of the drug: KNR = Kenral; SYN = Syncare; RHD = Rhodiapharm.

Source Ontario Ministry of Health, *Drug Benefit Formulary/Comparative Drug Index*; and Canadian Drug Manufacturers Association [1989, Tables 1-3].

will be higher and its returns lower. At the margin it may decide not to enter certain markets.

The fighting brand can obtain its Notice of Compliance well in advance of the generic brand and have a reasonably well-informed idea of the date on which the generic brand will appear in the formulary. It can thus safely enter the formulary six months before the generic producer.

The disadvantage of the fighting brand pre-empting the generic firm's entry is that the brand-name product forgoes sales at the high price. However, unlike the generic, the fighting brand can price quite close to the brand name and not expect any price reaction. The cost or forgone revenue to the brand-name firm may thus be quite small, depending in part on the degree to which the ODB accommodates the fighting brand's pricing strategy.

In order to examine the entry strategies of fighting brands, the ratios of the formulary prices of the first lower-priced interchangeable brand to the brand name were estimated for cardiovascular and central nervous system drugs – both high-volume therapeutic classifications. The sample included the lower-priced interchangeable brands that were first listed between 1989 and 1991. The first lower-priced interchangeable brand is divided into three categories: generic brands, fighting brands, and joint firsts (instances where the fighting and generic brand were listed simultaneously).

Table 6-6

Distribution and market shares of brand names, fighting brands, and generic brands of the 32 highest-dollar-volume drugs,[1] Ontario Drug Benefit, 1989-91[2]

	Number of brands and market share[3]																	
	1989						1990						1991					
	Brand name		Fighting brand[4]		Generic brand[5]		Brand name		Fighting brand		Generic brand		Brand name		Fighting brand		Generic brand	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Drug, strength, and dosage form																		
ranitidine HCl 150-mg tablet	1	10.6	0	...	1	89.5	1	8.2	1	4.0	2	87.9	1	3.8	1	3.1	3	93.1
diltiazem HCl 60-mg tablet	1	10.7	0	...	1	89.3	1	6.3	0	...	2	93.7	1	2.4	1	0.8	3	96.8
captopril 25-mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	22.7	1	18.2	1	59.1
salbutamol inh. 200-dose package	1	100.0	0	...	0	...	1	20.7	1	20.7	1	58.6	1	10.1	1	25.1	1	64.8
diltiazem HCl 30-mg tablet	1	10.1	0	...	1	89.9	1	4.8	0	...	2	95.2	1	2.5	1	0.8	3	96.7
nifedipine 20-mg LA capsule	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
diclofenac sodium 50-mg ent. tablet	1	100.0	0	...	0	...	1	7.2	0	...	1	92.8	1	3.4	0	...	2	96.6
nifedipine 10-mg capsule	1	10.8	0	...	2	89.2	1	9.6	0	...	2	90.4	1	5.1	0	...	3	94.9
diclofenac sodium 100-mg LA tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
glyburide 5-mg tablet	2	100.0	0	...	0	...	2	100.0	0	...	0	...	2	72.2	0	...	1	27.8
triazolam 0.25-mg tablet	1	17.7	1	82.3	0	...	1	4.2	1	44.0	1	51.8	1	2.4	1	39.5	2	58.1
amiloride HCl and hydrochlorothiazide 5-mg and 50-mg tablet	1	100.0	0	...	0	...	1	7.5	0	...	1	92.5	1	4.4	0	...	2	95.6
potassium chloride 8 mEq LA tablet[6]	1	98.5	0	...	3	1.5	1	98.7	0	...	3	1.3	1	98.8	0	...	3	1.2
digoxin 0.125-mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
atenolol 50-mg capsule	1	14.7	0	...	1	85.3	1	13.5	0	...	1	86.5	1	8.8	0	...	2	91.2
acetaminophen compound with codeine 30-mg tablet	2	94.0	0	...	3	6.0	2	93.0	0	...	3	7.0	2	93.1	0	...	3	6.9
sucralfate 1-g tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
verapamil HCl 80-mg tablet	1	100.0	0	...	0	...	1	43.5	1	56.5	0	...	1	13.8	1	70.4	2	15.8
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	1	6.2	0	...	2	93.8	1	5.2	0	...	2	94.8	1	3.1	0	...	3	96.9
enalapril maleate 5 mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
captopril 50-mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	20.2	1	18.5	1	61.2
domperidone 10-mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
acetylsalicylic acid 650-mg ent. tablet	1	20.7	0	...	1	79.3	1	17.9	0	...	1	82.1	1	16.2	0	...	1	83.8
furosemide 40-mg tablet	1	2.4	0	...	5	97.6	1	1.8	0	...	5	98.1	1	0.8	0	...	5	99.2
timolol maleate 0.5% oph. sol.	1	14.1	0	...	1	85.9	1	9.0	0	...	1	91.0	1	4.8	0	...	1	95.2
pentoxifylline 400-mg LA tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...

Table 6-6 (cont'd.)

	Number of brands and market share[3]																	
	1989						1990						1991					
	Brand name		Fighting brand[4]		Generic brand[5]		Brand name		Fighting brand		Generic brand		Brand name		Fighting brand		Generic brand	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
acetylsalicylic acid 325-mg ent. tablet	2	10.8	0	...	1	89.2	1	7.8	0	...	1	92.2	1	6.4	0	...	1	93.6
acetaminophen compound with codeine 15-mg tablet	2	94.5	0	...	3	5.5	2	92.3	0	...	3	7.7	2	91.6	0	...	3	8.4
famotidine 40-mg tablet	1	100.0	0	...	0	...	1	100.0	0	...	0	...	1	100.0	0	...	0	...
psyllium mucilloid oral pd. 340-g package[7]	1	20.3	0	...	4	79.7	2	20.5	0	...	3	79.5	2	12.9	0	...	4	87.1
beclomethasone dipropionate aero. pd. 200-dose package	2	100.0	0	...	0	...	2	100.0	0	...	0	...	2	100.0	0	...	0	...
lorazepam 1-mg tablet	1	8.0	0	...	2	92.0	1	6.1	0	...	2	93.9	1	4.3	0	...	3	95.7

1 As of March 1989.
2 1989 = January-June 1989 formulary; 1990 = July-December 1990 formulary; 1991 = February-June 1991 formulary.
3 Market shares are measured in terms of number of capsules, tablets, and so on in March 1989, September 1990, and March 1991.
4 Drugs marketed by Kenral, Syncare, and Rhodiapharm.
5 Drugs marketed by Apotex, Drug Trading Company, Frank W. Horner, Novopharm, and Technilab.
6 The generic brands are noninterchangeable.
7 All brands apart from Metamucil were classified as generic. In 1990 the brand-name owner introduced a sugar-free brand at the same price as the original brand.

Source: Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1989, September 1990, and March 1991; Ontario Ministry of Health [1989*a*, 1990*b*, 1991]; and Canadian Drug Manufacturers Association [1989, Tables 1-3].

The price of the first lower-priced interchangeable brand, relative to that of the brand name, is much lower for generic than for fighting brands (Table 6-7). The prices of the generic brands, all of which were introduced by Apotex and Novopharm, are 65 to 82 per cent of those of the brand names, substantial reductions.[17] The price reductions for the fighting brands are generally much lower.[18] Rhodiapharm does not offer a discount off the brand-name price with its Rhodis and Rhotrimine fighting brands. Kenral's and Syncare's fighting brands generally offer a minimal 5-per-cent discount. Kenral appears to have offered an unnecessarily large discount of 12.5 per cent on triazolam in 1989, since it reduced the discount on subsequent fighting brands to 5 per cent in 1990.

Table 6-7

Ratio of the Ontario formulary price[1] of the first lower-priced interchangeable brand listed to that of the brand-name drug for cardiovascular and central nervous system drugs, 1989-91[2]

	Ratio
First lower-priced interchangeable brand listed:	
Generic brands	
1989	
Apo-Atenol 50-mg tablet (APX)[3]	0.7865
Apo-Atenol 100-mg tablet (APX)	0.7877
Apo-Nadol 40-mg tablet (APX)	0.7878
Apo-Nadol 80-mg tablet (APX)	0.7508
Apo-Nadol 160-mg tablet (APX)	0.7880
Apo-Pindol 5-mg tablet (APX)	0.7284
Apo-Pindol 10-mg tablet (APX)	0.7280
Apo-Pindol 15-mg tablet (APX)	0.7280
Apo-Diltiaz 30-mg tablet (APX)	0.8185
Apo-Diltiaz 60-mg tablet (APX)	0.8183
1990	
Apo-Nifed 5-mg capsule (APX)	0.7538
Apo-Amilzide 5-mg and 50-mg tablet (APX)	0.6885
Novo-Difenac 25-mg ent. tablet (NOP)	0.7157
Novo-Difenac 50-mg ent. tablet (NOP)	0.7157
Apo-Keto (APX)	0.6801
1991	
Apo-Clonidine 0.1-mg tablet (APX)	0.7137
Apo-Clonidine 0.2-mg tablet (APX)	0.7135
Apo-Prazo 1-mg tablet (APX)	0.6467
Apo-Prazo 2-mg tablet (APX)	0.6458
Apo-Prazo 5-mg tablet (APX)	0.6788
Apo-Capto 12.5-mg tablet (APX)	0.7500
Fighting brands	
1989	
Rhodis 100-mg suppository (RHD)	0.9974
Rhotrimine 75-mg capsule (RHD)	1.0080
Triazolam 0.125-mg tablet (KNR)	0.8755
Triazolam 0.25-mg tablet (KNR)	0.8755
1990	
Verapamil 80-mg tablet (KNR)	0.9500
Verapamil 120-mg tablet (KNR)	0.9488
Alprazolam 0.25-mg tablet (KNR)	0.9496
Alprazolam 0.5-mg tablet (KNR)	0.9498
1991	
Rhodis-EC 50-mg ent. tablet (RHD)	0.6064
Rhodis-EC 100-mg ent. tablet (RHD)	0.6062
Joint firsts, 1991[4]	
Generic brands	
Apo-Capto 25-mg tablet (APX)	0.7499
Apo-Capto 50-mg tablet (APX)	0.7500
Apo-Capto 100-mg tablet (APX)	0.7499
Fighting brands	
Syn-Captopril 25-mg tablet (SYN)	0.9600
Syn-Captopril 50-mg tablet (SYN)	0.9500
Syn-Captopril 100-mg tablet (SYN)	0.9500

1 Price is defined as the BAP.
2 January and July formularies for 1989 and 1990; February for 1991.
3 Letters in parentheses are the companies that market the drug: APX = Apotex; RHD = Rhodiapharm; KNR = Kenral; NOP = Novopharm; SYN = Syncare.
4 There were no joint firsts in 1989 and 1990.

SOURCE Ontario Ministry of Health, *Drug Benefit Formulary/Comparative Drug Index*; and Canadian Drug Manufacturers Association [1989, Tables 1-3].

The strategy most frequently followed by fighting brands is to enter after the generic product is listed in the formulary; this occurred in 14 out of 20 cases (Table 6-5). Preemption was used on four occasions, and simultaneous appearance of the fighting and generic brands was used in two instances.

The prices charged by fighting brands and generic brands appear generally to be quite similar. The objective of fighting brands seems to be to meet, and not so much to beat, the competition and to slow the market penetration or growth of generic brands rather than to confine them to a very small market share.[19]

The Success of Fighting Brands in Capturing Market Share

The market share accounted for by the fighting brands is examined under four systems in three provinces: Nova Scotia's actual-acquisition-cost (AAC) system in the first

quarter of 1990 and the maximum-allowable-cost (MAC) system for the last quarter of 1990, Saskatchewan's standard-offer-contract (SOC) system over the period 1985-91, and Ontario's best-available-price (BAP) system for March 1989 to September 1990.

Ontario — The market shares of the brand names, fighting brands, and generic brands of all interchangeable drugs for which fighting and generic brands were listed in the January-June 1989 Ontario formulary are presented in Table 6-8, grouped according to the firm that marketed the fighting brand. Two price ratios are also presented. Despite some success by fighting brands, the generic brands generally retained a substantial market share. At one extreme is Rhodiapharm's fighting brand of trimipramine, which failed to sell one tablet three months after it was first listed in the Ontario formulary; at the other is Kenral's fighting brand of ibuprofen, which accounted for 80 per cent of the market, despite the fact that two generics entered at the same time (Table 6-5). The first generic listed had to be withdrawn because of concerns over its interchangeability, an extremely rare event. Even so, by September 1990 the market share of the generic brands was still only one third. In four cases, however, the generic firms were able to command a substantial share of the market, over 80 per cent, and in seven cases, over 50 per cent. Similar results were recorded for this set of drugs for September 1990. Not surprisingly, the prices of the fighting brands and the generic brands were very similar.

The market shares of the brand names, the fighting brands, and the generics of interchangeable drugs whose fighting brand was first marketed in Ontario between January 1988 and July 1990 are presented in Table 6-9. Fighting

Table 6-8

Market shares and price ratios of interchangeable drugs with fighting brands and generic brands, by marketing company, ODB formulary, March 1989

	Market share[1]			Price ratio	
	Brand name	Fighting brand[2]	Generic[3] brand	Lowest BAP to brand name[4]	Fighting brand to lowest generic brand
	(Per cent)				
Drug, strength, and dosage form[5]					
Kenral					
ibuprofen 400-mg tablet	5.9	79.8	14.3 (2)	0.3846	1.0000
prednisolone acetate 1% oph. sol.	22.1	75.9	2.0 (1)	0.4709	1.0644
sulfasalazine 500-mg ent. tablet	11.2	24.3	64.5 (2)	0.6240	0.9824
prednisone 5-mg tablet	5.3	28.9	65.8 (4)	0.7259	0.9899
haloperidol 5-mg tablet	5.2	3.8	91.0 (2)	0.4515	1.0000
erythromycin base 250-mg tablet	1.0	8.8	90.2 (2)	0.4458	1.1314
chloramphenicol 0.5% oph. sol.	19.7	45.7	34.5 (2)	0.5061	0.9459
sulfacetamide sodium 10% oph. sol.	2.1	14.9	83.0 (2)	0.4157	1.0483
Syncare					
naproxen 250-mg tablet	1.7	21.7	76.6 (2)	0.3737	0.9524
Rhodiapharm					
trimipramine 25-mg tablet	11.4	0	88.6 (1)	0.7252	1.3779

1 Measured in number of claims.
2 The brands sold by Kenral, Syncare, and Rhodiapharm.
3 The number of generic brands is in parentheses. A number of drugs manufactured by firms not usually thought of as generic were included: erythromycin base 250-mg tablet, Abbott Laboratories; chloramphenicol 0.5% oph. sol., Parke-Davis; and sulfacetamide sodium 10% oph. sol., Schering Canada. They were included because they appeared to be competing on a price basis.
4 In all instances, except chloramphenicol 0.5% oph. sol., the brand name had the highest BAP. In this case the brand-names's BAP was $0.3630, the highest BAP was $0.3867.
5 In some instances there was more than one strength for which a brand name, a fighting brand, and a generic brand were listed in the formulary. In these cases, the strength with the highest dollar volume in ODB claims for March 1989 was used.

Source Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989; Ontario Ministry of Health [1989a]; and Canadian Drug Manufacturers Association [1989, Tables 1-3].

brands do not appear to be successful in gaining market share, except where there is no generic competition. In the 10 instances where there is such competition, by March 1991 the generic brands had captured at least half of the market in eight instances, with an average of 67.4 per cent. Even when the fighting brand entered before the generic brand, as occurred with triazolam 0.25-mg tablets and alprazolam 0.25-mg tablets, this appears to have slowed but not stopped generic-brand market penetration. In the four instances where the drug is a leading seller, generic brands were also usually able to command substantial market share (Table 6-6).

The results presented in Tables 6-6, 6-8, and 6-9 suggest that in Ontario the marketing of fighting brands to compete with generic brands has not led to the demise of generic brands. They are able to obtain and retain substantial market share, whether competing with more recently marketed fighting brands or in a market for a high-dollar-volume drug.

Saskatchewan — The fighting brands marketed by Kenral, Syncare, and Rhodiapharm that won standing offer contracts in Saskatchewan over the period 1985-91 are presented in Table 6-10. The contracts are offered for six-month periods; therefore, the table is divided into 14 six-month periods over the seven years. In general, it would seem that fighting brands have not been conspicuously successful in gaining market share.[20] Syncare was much more successful than Kenral in winning SOCs. However, a number of Syncare's successful fighting brands have not been in the market long; in order to establish whether this is more than a temporary success, a longer time-frame is necessary.

Nova Scotia — Market share data for those drugs for which there were fighting brands and generic brands are presented for the first and last quarters of 1990 in Table 6-11. These periods were chosen because in the intervening period Nova Scotia changed from an AAC system to a MAC system of drug reimbursement very similar to Ontario's BAP system.

In the early part of 1990 the brand names were frequently able to command a substantial market share; for example, sulfasalazine 500-mg enteric tablets, chloramphenicol 0.5 per cent ophthalmic solution, ranitidine HCl 150-mg tablets, pindolol 5-mg tablets, nadolol 80-mg tablets, and trimipramine 25-mg tablets. Furthermore, the brand-name prices were substantially above the prices of the lowest-priced brands, whether they were generic brands or fighting brands. Without exception, the generic brands commanded a larger market share than the fighting brands, sometimes by a substantial margin.

In the last quarter of 1990 the market shares of all the brand-name firms shrank, in some cases by a substantial amount. For example, the brand-name firm held 74.1 per cent of the ranitidine HCl 150-mg tablets in January-March 1990, but over the period October to December its market share declined to a mere 2.9 per cent. In the first period, nadolol 80-mg tablets had 91.1 per cent of the market; this had declined to 10.4 per cent by the last period.

All the fighting brands and generic brands increased their market shares between the first and last quarter of 1990. Overall, generic brands had more than 50 per cent of the market for seven out of the eleven drugs in Table 6-11. Fighting brands held more than 50 per cent of the market in two cases. In other words, the generic brands usually had a larger market share than the fighting brands.

Turning now to the price ratios in Table 6-11, in the last quarter of 1990 the fighting brands were priced either the same or somewhat higher than the generic brand. The premium commanded by the brand name fell considerably with the switch from AAC to MAC, particularly for ibuprofen 400-mg tablets, haloperidol 5-mg tablets, and naproxen 250-mg tablets.

The Impact of Fighting Brands

The impact of fighting brands can be examined from a number of point of views; the one selected here is price. More specifically, the ability of fighting brands to remove the threat of lower-priced generic brands from the marketplace – with the consequent increase in the price of drugs – is examined. We distinguish between the short-run and the longer-run impacts of fighting brands.

The Short Run — In the short run the presence of fighting brands results in lower drug prices. When the fighting brand enters before the generic brand, the benefits of price competition appear earlier. This benefit can be overstated, in view of the small price difference between the brand name and the fighting brand when the fighting brand enters before the generic brand. Nevertheless, the presence of the fighting brand may force the first generic brand to offer a bigger discount.

The benefits of fighting brands with respect to price are not limited to those instances where the fighting brand preempts the generic brand. When the fighting brand enters after or at the same time as the generic brand, it is likely to result in much more fierce price competition. This confirms the results reported in Chapter 5 concerning the spread in Ontario and the difference in prices between Saskatchewan and Ontario. In virtually all instances when the ODB

Table 6-9

Market shares of brand names, fighting brands, and generic brands of interchangeable drugs over a three-year period,[1] Ontario Drug Benefit, 1989-91

	Market share		
	Brand name	Fighting brand[2]	Generic brand[3]
		(Per cent)	
Drug, strength, and dosage form[4]			
January 1988			
haloperidol 5-mg tablet			
March 1989	6.4	3.2	90.4
September 1989	3.6	2.6	93.8
March 1990	2.5	3.2	94.3
September 1990	3.3	3.0	93.6
March 1991	2.1	3.4	94.6
January 1989			
trimipramine 25-mg tablet			
March 1989	11.4	–	88.6
September 1989	10.2	–	89.8
March 1990	6.8	3.9	89.3
September 1990	6.8	10.6	82.5
March 1991	3.8	12.4	83.8
triazolam 0.25-mg tablet			
March 1989	17.4	82.6	...
September 1989	7.0	58.5	34.4
March 1990	4.4	51.6	44.0
September 1990	4.2	44.0	51.8
March 1991	2.3	38.9	58.8
July 1989			
pindolol 5-mg tablet			
March 1989	20.2	...	79.8
September 1989	11.9	1.3	86.7
March 1990	8.5	7.0	84.4
September 1990	8.8	10.4	80.8
March 1991	5.6	11.9	82.5
January 1990			
nadolol 80-mg tablet			
March 1989	21.1	...	78.9
September 1989	13.4	...	86.6
March 1990	8.8	1.5	89.6
September 1990	10.9	7.1	82.0
March 1991	6.0	6.9	87.1
July 1990			
salbutamol inh. 200-dose package			
March 1989	100.0	...	...
September 1989	25.4	...	74.6
March 1990	18.4	...	81.6
September 1990	20.7	20.7	58.6
March 1991	9.0	25.2	65.8
verapamil 80-mg tablet			
March 1989	100.0	...	...
September 1989	100.0	...	...
March 1990	100.0	...	...
September 1990	43.5	56.5	...
March 1991	14.0	69.6	16.3
alprazolam 0.25-mg tablet			
March 1989	100.0	...	...

Table 6-9 (cont'd.)

	Market share		
	Brand name	Fighting brand[2]	Generic brand[3]
	(Per cent)		
September 1989	100.0	...	...
March 1990	100.0	...	...
September 1990	44.1	55.9	...
March 1991	13.8	59.6	26.6
ranitidine HCl 150-mg tablet			
March 1989	10.3	...	89.7
September 1989	10.6	...	89.4
March 1990	6.7	...	93.3
September 1990	8.2	4.0	87.9
March 1991	3.6	3.0	93.4
ketoprofen 50-mg capsule			
March 1989	100.0	...	...
September 1989	100.0	...	...
March 1990	52.9	...	47.1
September 1990	28.1	6.1	65.8
March 1991	22.5	12.6	64.9

1 Sample consists of drugs whose fighting brand first entered the formulary between January 1988 and July 1990.
2 The brands sold by Kenral, Syncare, and Rhodiapharm.
3 All other brands, typically sold by Apotex and Novopharm.
4 In some instances there was more than one strength listed. The strength with the highest dollar volume of ODB claims in March 1989 was used.
Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March and September 1989, 1990 and March 1991; Canadian Drug Manufacturers Association [1989, Tables 1-3]; and Table 6-5.

lowered the BAP in February 1991, a fighting brand was competing with a generic brand.

There is another less obvious way in which fighting brands reduce prices. Because of the similarity between the fighting brand and the brand name, the presence of the former helps to undermine the no-substitution campaign of the brand-name firms. For example, in some instances physicians write no-substitution prescriptions because a patient is allergic to the nonactive ingredients in the generic product; this problem does not occur with the fighting brand. The net result is a smaller market share for the higher-priced brand name and a larger market share for the fighting brand.

The Longer Run — In the longer run the impact of fighting brands is more difficult to predict. One view sees them assuming greater importance and gradually eliminating the generic firms as a source of competition. Fighting brands have been used in other contexts by dominant firms to neutralize, if not eliminate, new competitors (e.g., for matches [Commissioner, Combines Investigation Act 1950], shipping [Yamey 1972], and gasoline retailing [Bertrand 1981, vol. 6]). The net result would be higher drug prices.

This view is not entirely implausible. Fighting brands are increasing in importance. Kenral and Syncare are expanding their product line. At the same time, as the impact of Bill C-22 is felt, there will be a once-and-for-all slowdown of seven to ten years in the supply of new high-volume drugs eligible for compulsory licensing. Thus there is a window of opportunity for fighting brands to reduce, if not eliminate, the threat of generic drug firms.

Seen in this context the introduction of fighting brands cannot be considered classic predation – pricing below cost, with the intent of driving a rival out of business, and then raising the price to recoup the losses – in the way that Hoffman-LaRoche's actions were. Rather, the evidence is consistent with the view that fighting brands are designed to limit the market share and profitability of generic firms' existing products, and thus serve as a disincentive for generic firms to enter new markets – specifically the market for high-dollar-volume drugs, entry into which the recent amendments to the Patent Act have introduced a seven-to-ten-year delay. In other words, the fighting brands are a credible threat that "deters potential entrants by reducing the expected returns which the entrant anticipates when considering entry" [Bertrand 1981, vol. 6, 34].

This possibility was clearly recognized in earlier literature on fighting brands. In his study of fighting ships – ships sent by the dominant firms in the industry to exclude low-priced competitors from picking up cargo – Yamey observes that:

Table 6-10

Firms awarded standing offer contracts to supply drugs for which there was a fighting brand,[1] by marketing firm, Saskatchewan, 1985-91

	Winning firm[2]														Ratio of contracts won to contracts bid on, fighting brands[3]
	1985		1986		1987		1988		1989		1990		1991		
	Jan.	July	Jan.	July	Jan.	July	Jan.	July	Jan.	July	Jan.	July	Jan.	July	
Drug, strength, and dosage form[4]															
Kenral (KNR)															
ibuprofen 400-mg tablet	**APX**[5]	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	0/14
sulfasalazine 500-mg ent. tablet	ICN	ICN	ICN	ICN	**PMS**	**ICN**	**ICN**	**ICN**	**KNR**	**PMS**	**PMS**	**PMS**	**PMS**	**PMS**	1/10
prednisone 5-mg tablet	**KNR**	**KNR**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	**APX**	2/14
haloperidol 5-mg tablet	...	...	NOP	NOP	NOP	NOP	**NOP**	**NOP**	**KNR**	**NOP/ APX**	**APX**	**APX**	**APX**	**TCH**	1/8
erythromycin 250-mg tablet	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	**ABB**	...	**ABB**	0/10
sulfacetamide sodium 10% oph. sol.	ALL	ALL	ALL	ALL	ALL	ALL	ALC	ALC	ALC	ALC	AKN	AKN	AKN	AKN	0/0
salbutamol inh. 200-dose package	...	...	...	...	...	...	...	...	...	...	GLA	KNR	...	...	0/0
verapamil HCl 80-mg tablet	...	...	...	...	...	...	...	...	...	...	...	...	**APX**	**APX**	0/2
alprazolam 0.25-mg tablet	...	...	...	...	...	...	...	...	...	...	...	...	**APX**	**APX**	0/2
ranitidine 150-mg tablet	...	...	...	...	...	...	APX	APX	APX	APX	**APX**	**APX**	**APX**	**APX**	0/4
triazolam 0.25-mg tablet	...	...	...	...	...	...	...	...	...	**APX**	**APX**	**APX**	**APX**	**APX**	0/5
Syncare (SYN)															
naproxen 250-mg tablet	**SYN**	**APX**	**APX**	**APX**	**SYN**	**SYN**	**SYN**	**SYN**	**SYN**	**NOP**	**NOP**	**NOP**	**NOP**	**NOP**	6/14

pindolol															
5-mg tablet	...	...	...	...	...	...	...	...	APX	**APX**	**SYN**	**SYN**	**APX**	**APX**	2/5
nadolol															
80-mg tablet	...	...	...	...	...	...	...	...	APX	APX	**APX**	**APX**	**SYN**	**SYN**	2/4
diltiazem HCl															
60-mg tablet	...	...	...	...	...	...	...	...	**APX**	APX	APX	APX	**SYN**	**NOP**	1/2
captopril															
25-mg tablet	...	...	...	...	...	...	...	...	...	...	...	...	**SYN**	**SYN**	2/2
Rhodiapharm (RHD)															
trimipramine															
25-mg tablet	...	...	...	...	...	...	...	...	...	...	...	**APX**	**APX**	**APX**	0/3
ketoprofen															
50-mg ent. tablet	...	...	...	...	...	...	...	...	...	...	...	...	RDH	RDH	0/0

1 Fighting brands that are listed in the Saskatchewan formulary as of July 1990/January 1991 and for which there was an SOC in the period 1985-91. The only exceptions are sulfacetamide sodium 10% oph. sol., salbutamol inh. 200-dose package, and ketoprofen 50-mg ent. tablet for which there were no fighting brand listed.
2 ABB = Abbott Laboratories; AKN = Akon Pharmaceuticals Canada; ALC = Alcon Canada; ALL = Allergan Pharmaceuticals; APX = Apotex; ICN = ICN Canada; NOP = Novopharm; PMS = Pharmascience; TCH = Technilab.
3 When a generic brand is also present.
4 On some occasions there was more than one strength listed. The strength with the highest dollar volume of ODB claims in March 1989 was used.
5 In those instances where there were a fighting brand, a brand name, and at least one other brand, the winning firm is indicated in bold typeface.
Source Canadian Drug Manufacturers Association [1989, Tables 1-3]; and Saskatchewan Department of Health, *Formulary*.

Table 6-11

Market shares and price ratios of interchangeable drugs with fighting brands and generic brands,[1] by marketing firm, Nova Scotia Pharmacare, 1990

Drug, strength, and dosage form[5]	Market share[2]			Price ratio	
	Brand name	Fighting brand[3]	Generic brand[4]	Lowest price to brand name	Fighting brand to lowest generic brand
	(Per cent)				
Kenral					
ibuprofen 400-mg tablet					
January-March	48.0	20.1	31.9 (2)	0.3019	1.0541
October-December	3.6	32.8	63.7 (2)	0.6634	1.0120
sulfasalazine 500-mg ent. tablet					
January-March	89.0	2.4	8.6 (1)	0.5432	0.6916
October-December	15.2	68.4	16.4 (1)	0.9870	0.9818
prednisone 5-mg tablet					
January-March	57.3	4.2	38.5 (2)	0.8115	1.0202
October-December	39.2	8.5	52.3 (2)	1.0000	0.9907
haloperidol 5-mg tablet					
January-March	34.1	2.8	63.0 (2)	0.3856	1.0455
October-December	3.0	15.9	81.1 (2)	0.9589	1.0478
chloramphenicol 0.5% oph. sol.					
January-March	76.7	--	23.3 (1)	0.9584	...
October-December	46.2	27.5	26.3 (1)	0.9548	1.0178
triazolam 0.25-mg tablet					
January-March	...	...	...	...	...
October-December	6.6	82.4	11.1 (1)	1.0000	1.0398
ranitidine HCl 150-mg tablet					
January-March	74.1	--	25.9 (1)	0.7334	...
October-December	2.9	22.5	74.6 (2)	0.9778	1.0142
Syncare					
naproxen 250-mg tablet					
January-March	30.1	19.3	50.5 (2)	0.3260	1.1784
October-December	3.5	30.6	65.9 (2)	0.8363	0.9979
pindolol 5-mg tablet					
January-March	94.0	--	6.0 (1)	0.7043	...
October-December	9.7	46.6	43.6 (1)	0.9699	0.9927
nadolol 80-mg tablet					
January-March	91.1	--	8.9 (1)	0.7538	...
October-December	10.4	32.7	56.8 (1)	0.9453	1.0578
Rhodiapharm					
trimipramine 25-mg tablet					
January-March	93.6	...	6.4 (1)	0.7330	...
October-December	34.2	1.2	64.6 (1)	0.9959	1.0359

1 In either January-March or October-December 1990.
2 Measured in quantity of drug dispensed.
3 The brands sold by Kenral, Syncare, and Rhodiapharm.
4 All other brands, the number of which is indicated in parentheses. In the case of chloramphenicol 0.5% oph. sol., Parke-Davis was classified as the sole generic because it had the lowest price.
5 In some instances there was more than one strength listed. The strength with the highest dollar volume of ODB claims in March 1989 was used.

Source: Based on data from Maritime Medical Care; Canadian Drug Manufacturers Association [1989, Tables 1-3]; and Nova Scotia Health Service and Insurance Commission, *Prescription Drug Formulary*.

The point is frequently made in the literature on predatory pricing that the practice makes little sense where entry into the industry or trade in question is easy. However . . . predatory pricing or the threat of its use, may itself operate as an effective hindrance to new entry even in situations where the conventional barriers to entry are weak or absent [1972, 141].

This statement applies, it could be argued, *mutatis mutandis*, to fighting brands that have the effect of limiting the market share and profitability of new firms.

It is not at all clear, however, that generic firms are about to disappear in the short-to-medium term because of the presence of fighting brands. Although fighting brands are becoming increasingly important, a number of high-dollar-volume drugs do not have fighting brands, even though the generic brand has been on the market for a number of years. Even where a fighting brand has entered, the generic brand retains a large share of the market, sometimes for a sufficiently long duration – seven years in some cases – that the generic firm must be making at least a normal rate of return. Furthermore, it is not at all clear that Bill C-22 will result in generic firms being excluded from high-dollar-volume markets for seven to ten years. An example of a high-dollar-volume market which they anticipate entering is that for sustained release or long-acting dosage forms. There may also be other drugs – perhaps lower-volume products, or more complex dosage forms such as injectables sold primarily to the hospital market – that the generic firms have largely ignored until now in their race to be first into the high-dollar-volume markets. A couple of Canadian generic firms are also challenging the validity of drug patents held by brand-name firms.

The experience of the deployment of fighting brands in other industries may not be applicable to the drug industry. The leading generic drug manufacturers are not small, marginal, unprofitable firms, but large, thriving, profitable, and successful ones. In terms of the number of prescriptions dispensed in Canada, the two leading generic firms – presumably Apotex and Novopharm – had 11.9 per cent and 6.6 per cent of the market respectively in 1988 [Pharmaceutical Inquiry of Ontario 1990*a*, 64].[21] Generic drug firms had rates of return that were well above the all-manufacturing average in 1987. For example, their after-tax profit on capital employed was 18.3 per cent, the figure for all manufacturing was 8 per cent. The brand-name manufacturers were even more profitable, at 25.5 per cent [Ontario Ministry of Industry, Trade and Technology 1991].

The presence of fighting brands has not prevented the recent entry of two new generic firms. Genpharm, a sister company of the largest independent generic firm in the United Kingdom, entered the July 1990 Ontario formulary with two products, tamoxifen citrate and baclofen, and the February 1991 formulary with glyburide. Genpharm's products were the first generic brands of baclofen and glyburide to be listed. Nu-Pharm, a Canadian firm that markets products that are manufactured by Apotex, entered the January 1991 Saskatchewan formulary with 23 drugs, including such big sellers as ranitidine HCl and diltiazem HCl. It entered the February 1991 Ontario formulary on a similar scale.

Policy Options

If fighting brands are designed to neutralize or eliminate generic drug manufacturers from new drug markets so as to maintain prices, it is doubtful, based on the evidence, that they will succeed. Rather, fighting brands seem to be providing, in the short run at least, additional competition that leads to lower prices. Nevertheless, there are some steps that purchasers of drugs could take if fighting brands seriously threaten the viability of the generic sector, with the rise in drug prices that this would entail. These include:

- the provincial drug plan could enter into contracts with the manufacturers of generic brands of selected high-dollar-volume drugs, thereby excluding the fighting brand;

- a waiting period of, say, a year could be mandated before a fighting brand is listed;

- federal competition authorities could be kept informed of all developments with respect to fighting brands, so that if enough evidence is available, appropriate action can be taken;[22]

- the price for the corresponding interchangeable brand-name drug could be kept at no more than the price of the fighting brand for *all* prescriptions for that drug in the province.

Shifting Demand: Long-Acting or Slow-Release Dosage Forms

The final response by brand-name drug manufacturers to the competition from generic drug manufacturers is to introduce dosage forms that have been decreed, at least up until late 1991, as noninterchangeable. Drugs can be sold in a variety of dosage forms – for example, tablets, capsules, injectables, ointments, and aerosols – and strengths. The dosage form and strength marketed by the brand-name firm depend on where it believes the market demand is likely to be greatest. Usually, when a generic firm markets an interchangeable drug, it selects the best-selling dosage forms and strengths, typically immediate-release solid oral dosage forms such as capsules and tablets (there are a few exceptions, such as Apotex's salbutamol inhaler).

Faced with generic competition on a particular dosage form and strength, the brand-name manufacturer can

attempt to shift demand to a close substitute, which will either delay the onset of generic competition or remove the threat entirely. The close substitute could be not only a different dosage form but also a different product. An example of a company using a different product as a close substitute is Hoffman-LaRoche's policy of accelerating the shift of the demand away from chlordiazepoxide to diazepam when generic competitors appeared [Gorecki 1986*b*]. Attention is devoted here, however, only to instances where different dosage forms are used as close substitutes.

Long-acting or slow-release dosage forms of the same strength for the same drug have long been noninterchangeable in Ontario and other provinces. Under these conditions the ODB pays for the brand dispensed at that brand's BAP. Furthermore, not only is there no incentive for the pharmacist to product select a lower-priced brand, but there is a positive disincentive. Pharmacists have no legal protection when they product select a noninterchangeable drug. Not surprisingly, brand-name manufacturers have been able to retain both market share and a price premium in these circumstances. For example, for potassium chloride 8 mEq long-acting tablets there is one brand name and three generic brands. In March 1989 the brand-name firm accounted for 98.3 per cent of all ODB claims, with a BAP that was about three times that of the lower-priced generic brands.

When a brand-name manufacturer encounters a lower-priced generic brand, one strategy to retain its market share is to shift demand to a long-acting dosage form. This requires persuading physicians to prescribe it and drug reimbursement programs to make it an eligible benefit. The new long-acting dosage form has to therefore offer an improvement over the immediate-release dosage form that has been on sale for a number of years. One such rationale could be that the long-acting form has a new indication. Another could be that there is better patient compliance if the long-acting dosage form needs to be taken less frequently than the immediate-release form.

The Incidence and Importance of Modified Release Dosage Forms

Table 6-12 lists the market shares, measured by the number of claims, of the long-acting and immediate-release dosage forms of the top-selling drugs for which a long-acting dosage form was marketed in 1989. There are only a small number of drugs for which there are long-acting dosage forms. For two drugs, potassium chloride and pentoxifylline, only the long-acting form is available. For four of the drugs, both dosage forms are available. The long-acting dosage forms accounted for over 40 per cent of the nifedipine and diclofenac sodium markets in March 1989, but a much smaller proportion of the markets for diltiazem HCl and verapamil, since they were both first listed in the formulary only in January 1989. However, by September 1990 the market shares of the long-acting dosage forms of these four drugs had increased to at least one third, and their mean market share was approximately 50 per cent.

Table 6-12

Market shares and number of strengths of long-acting and immediate-release dosage forms of the highest-dollar-volume drugs,[1] Ontario Drug Benefit, 1989-90[2]

	Market share and number of strengths[3]			
	1989		1990	
	Immediate release[4]	Long acting	Immediate release	Long acting
Drug				
diltiazem	95.3 (2)	4.70 (2)	69.2 (2)	30.8 (3)
nifedipine	52.4 (2)	47.6 (1)	28.7 (3)	71.3 (2)
diclofenac sodium	58.3 (4)	41.7 (1)	53.1 (4)	46.9 (1)
potassium chloride	0 (0)	100.0 (5)	0 (0)	100.0 (6)
verapamil	81.4 (2)	18.6 (1)	57.1 (2)	42.9 (1)
pentoxifylline	0 (0)	100.0 (1)	0 (0)	100.0 (1)

1 The 32 highest-dollar-volume drugs paid for by the ODB in March 1989.
2 Formularies of January-June 1989 and July-December 1990.
3 Market shares, measured in number of claims, are for March 1989 and September 1990. The number of strengths is in parentheses.
4 These are usually solid dosage forms, although diclofenac sodium includes suppositories.
Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1989 and September 1990; and Ontario Ministry of Health [1989*a*, 1990*b*].

Diltiazem HCl, nifedipine, and verapamil are the drugs for which there seems to be most evidence that long-acting dosage forms are used to protect market share. In all three instances the long-acting forms are listed for indications that the immediate-release dosage forms do not have, as evidenced by the fact that they are listed in the formulary in a different therapeutic classification from that of the immediate-release dosage forms. In January 1989 both sets of dosage forms were confined to the cardiac therapeutic classification, but by July 1990 the long-acting dosage forms were listed in the hypotensive therapeutic classification for all three drugs.[23] Novopharm argues that long-acting dosage forms of diltiazem and nifedipine were introduced as an antigeneric marketing tactic [1988, 6-7]. Fighting brands of diltiazem HCl and verapamil were also marketed in 1990/91 (Table 6-5).

Assessment

While there is evidence that certain long-acting dosage forms were introduced to shift demand away from those dosage forms for which the brand name is facing or is expected to face generic competition, there is also evidence that these long-acting forms offer advantages over the immediate-release dosage forms. They have, after all, been approved in their new uses by the federal health regulatory authorities, recommended for inclusion in the provincial formulary by the Drug Quality and Therapeutics Committee, and prescribed by many physicians.

The argument that long-acting dosage forms are only a way of shifting demand, with no offsetting benefits, is a substitution effect, while if there are substantial new advantages, then there should also be a market expansion effect. To isolate the impact of each would require a careful analysis of the advantages and disadvantages and the determinants of the demand for each dosage form, which was not possible for this study. A more limited exercise was, however, undertaken. Figure 6-1 presents the number of claims for the immediate-release and long-acting dosage forms of the four drugs in Table 6-12 for which both were available. These must be interpreted with care, since we were not able to predict what demand would have been without the long-acting dosage forms.

In all cases the marketing of the long-acting dosage forms is associated with a decline in the number of claims for the immediate-release dosage forms. The exception is diclofenac sodium, where it took several years before the claims for the immediate-release forms declined. In contrast, there was healthy growth in the sales of the long-acting dosage forms from their introduction. This growth in sales more than offset the decline in claims for the immediate-release form. Thus there is evidence of both market expansion and displacement.

Policy Options

How can the appropriate incentives be provided to ensure that resources are allocated in an efficient manner? If long-acting dosage forms are designed to shift demand but provide little or no therapeutic improvement over existing lower-priced dosage forms, this is a waste of resources from society's point of view. If, on the other hand, there are genuine advantages to long-acting dosage forms, the issue is how to allocate consumption between the more and less expensive dosage forms. There are some possible policy measures that could be taken to ensure the efficient allocation of resources. These include:

- Permit long-acting dosage forms to be interchangeable. There is a movement in this direction. A recent report by a federal task force sets out guidelines for the interchangeability of long-acting dosage forms [Expert Advisory Committee on Bioavailability 1990*b*]. The Ontario government has undertaken a similar exercise, which is expected to be completed in late 1991 or early 1992.

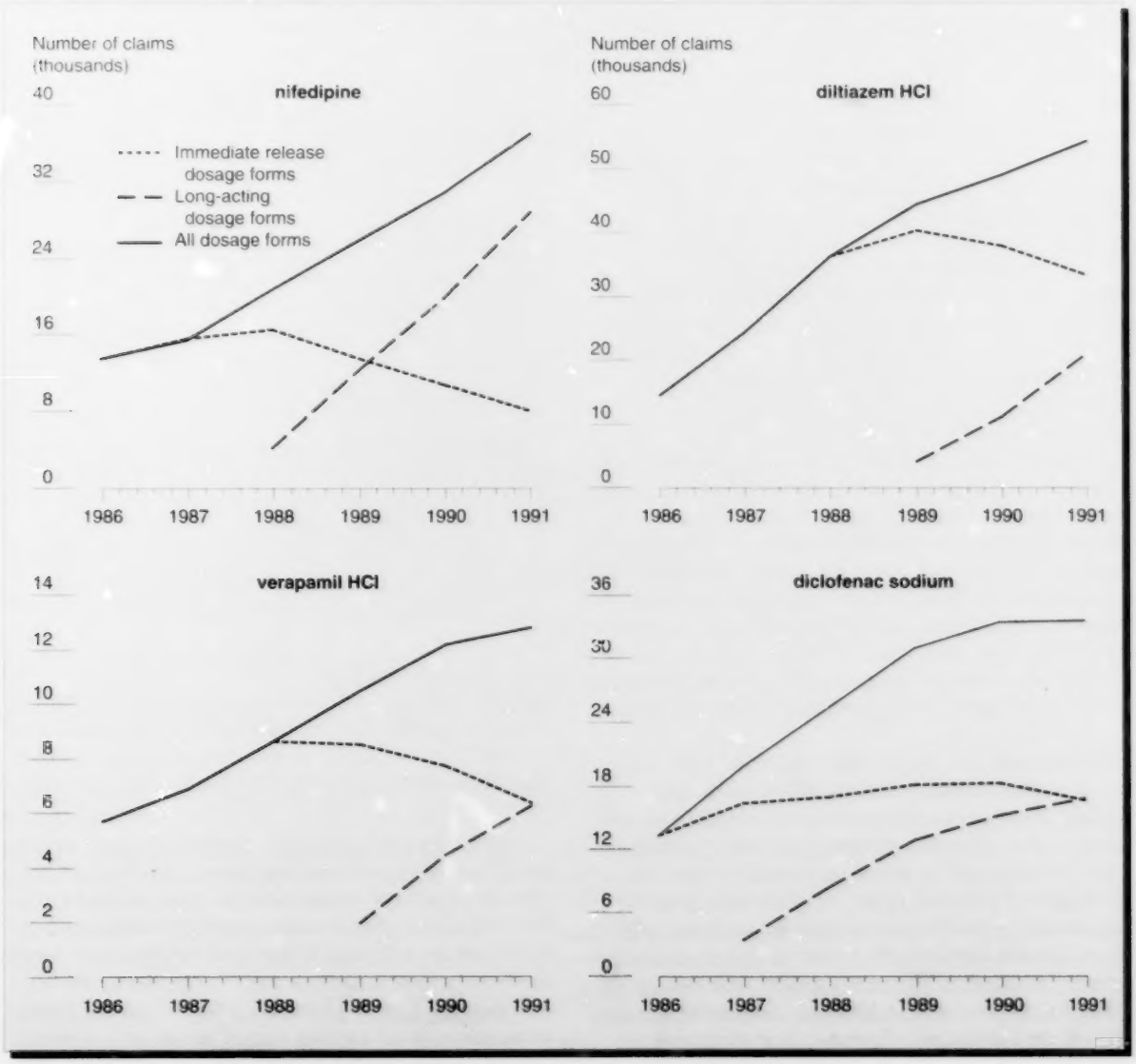
- When the new indications apply equally well to both dosage forms, but only the long-acting dosage form has regulatory approval for them, provincial governments could reimburse for long-acting dosage forms at a price no higher than that of the immediate-release dosage form equivalent.

- If the long-acting dosage form performs tasks that the immediate-release dosage form cannot, and the extra benefits are equal to or exceed the extra costs, the uses for the long-acting dosage form could be strictly confined to those tasks, and the information conveyed to physicians. Since the manufacturer is likely to market very heavily the long-acting dosage form in preference to the one that has generic competition, the long-acting dosage form is likely to be used more frequently than is cost-effective. There is an underprovision of information on the merits of the two dosage forms.

More radical than any of these suggestions was Saskatchewan's announcement in February 1991 that as of July 1991 it would not pay for long-acting dosage forms where there were immediate-release dosage forms listed in the formulary. The province has subsequently decided that more time is needed to undertake the necessary review, so delisting is unlikely to occur until 1992.[24]

Figure 6-1

Number of monthly claims for various dosage forms of the highest-dollar-volume drugs, Ontario Drug Benefit, March 1986 to March 1991



SOURCE Ontario Drug Benefit, "Formulary utilization," computer printouts.

Conclusions

What is being played here is a complex game. From the late 1960s to the mid-1980s the federal and provincial governments successfully transferred market share from higher-priced brand-name products to lower-priced generic brands. The response of the brand-name firms has been to introduce these three marketing strategies to limit the impact of generic drugs. That these strategies are being employed by brand-name firms is a sign of the success, rather than the failure, of provincial government policies to encourage the dispensing of lower-priced interchangeable drug products.

The ball is firmly in the court of the provincial governments. They have to decide how or indeed whether to respond to these marketing strategies of the brand-name firms. Policies on no-substitution prescriptions and slow-release dosage forms have already been implemented or are about to be implemented in a number of provinces. The progress of fighting brands needs to be carefully watched in order to ensure that in the long run they do not substantially reduce the benefits of lower-priced generic brands.

7 Promoting Cost-Effective Prescribing

Patient/consumer copayment, interchangeability, price and product selection rules designed to lower drug prices, and the elimination of no-substitution prescriptions are all measures aimed at containing public and private drug expenditures. Important as these cost containment measures are, one should not ignore the benefit side of the equation. Analysts are increasingly questioning the assumption that, at the margin, the benefits of drug therapy are worth the costs [e.g., Carruthers et al. 1987]. There is a growing concern that in many areas of medical practice much of the care provided is cost ineffective [e.g., Ontario Ministry of Health 1990*d*].

In this chapter the procedures and mechanisms that Ontario has introduced to promote cost-effective use of drugs are analysed and policy options presented. This discussion centres on the physician's prescribing decision. We examine first, however, the case for government intervention in this decision. Since the Ontario system resembles those of other provinces in varying degrees, reference will be made to the situation beyond Ontario's borders.

Rationale for Intervention

The rationale for government intervention with respect to cost-effective drug prescribing revolves around two interconnected sets of factors. The first is the scale and complexity of the prescribing decision for the physician. The second is the various incentives arising from the fact that separate parties demand, pay for, and consume drugs.

The Prescribing Decision

To ensure that the patient/consumer receives the most cost-effective drug, the physician has to absorb, screen, process, and evaluate a large amount of information [Doubilet et al. 1986]. The physician has to first diagnose the condition of the patient/consumer, decide on the right treatment, and then – if appropriate – consider the choice of drug and brand. Thus the physician is required not only to be aware of medical advances and developments, but also of current developments in drug therapy.

Several considerations must be taken into account when prescribing drug products. They include the uses or indications for which the drug has received regulatory approval; its price; the side effects or contraindications; the degree of substitutability and complementarity with other drugs, drug products, and alternative medical procedures; the nonactive ingredients or excipients; the variety of dosage forms and strengths; and whether it is a single-source or interchangeable drug. These characteristics can change. Different dosage forms and strengths of a given drug are introduced; new indications for a drug are found, either as a result of research or experience with its use in the general population; and better drugs are introduced.

Volume of Drug Products

At present approximately 2,500 drug products covering 700 different drugs are eligible for reimbursement under the Ontario Drug Benefit (ODB) program.[1] This number is not static. Products are constantly being added and, less frequently, subtracted. In general, there has been a steady annual increase in the number of drug products, both single source and interchangeable. The total number of drug products eligible for reimbursement under the ODB increased by one third between 1979 and 1988: single-source products by 58 per cent and interchangeable drugs by 14 per cent (Table 7-1).[2]

Turnover in Leading Drugs

There is considerable turnover in the leading drugs (Table 7-2). Between 1979 and 1989 quite dramatic changes took place. Of the 32 ODB highest-dollar-volume drugs in 1989, only 40 per cent were eligible benefits in Ontario a decade earlier. Among the 10 highest-dollar-volume drugs, only two were available a decade earlier. A closer examination of the table reveals other noteworthy changes. Two of the 13 drugs that were available in 1979 and 1989 have changed from single source to interchangeable. Hence, even for those drugs that remained in the top 32, change occurs because of the different status of the drug.

Similar results are reported for New Brunswick, whose plan coverage is similar to Ontario's. There it was found that:

Table 7-1

Single-source and interchangeable drugs in the Ontario formulary,[1] 1979-88

Formulary issue	Total number of drug products[2]	Percentage accounted for by interchangeable drugs of all ODB claims			Drug cost per claim		
		Drug products	Claims	Drug cost	Single source	Inter-changeable	All
		(Per cent)			(Dollars)		
1979							
January-June	1,878	60.6	69.5	55.3	5.66	3.07	3.96
July-December	1,904	60.3	68.6	53.7	6.18	3.29	4.20
1980							
January-June	1,964	60.1	67.9	52.3	6.48	3.35	4.36
July-December	1,994	60.7	66.6	49.3	7.18	3.50	4.73
1981							
January-June	2,037	60.2	65.5	47.9	7.59	3.68	5.03
July-December	2,038	58.9	64.1	45.5	8.40	3.93	5.54
1982							
January-June	2,061	52.2	61.7	39.3	8.78	3.81	5.99
July-December	2,119	52.0	62.0	42.1	10.14	4.50	6.64
1983							
January-June	2,121	51.2	62.7	44.9	10.19	4.96	6.91
July-January 1984	2,177	49.9	61.5	41.8	11.01	4.98	7.29
1984							
February-June	2,227	49.9	61.2	35.8	11.56	4.09	6.99
July-December	2,302	51.0	60.8	35.8	12.33	4.43	7.53
1985							
January-June	2,309	51.0	60.8	34.8	13.14	4.54	7.91
July-December	2,297	50.9	59.2	32.5	13.92	4.62	8.42
1986							
January-June	2,289	51.2	58.3	31.6	13.88	4.59	8.46
July-November	2,298	50.9	57.1	30.0	14.55	4.68	8.91
December	2,339	51.0	60.5	22.7	17.51	3.36	8.95
1987							
January-June	2,445	50.3	59.3	21.4	17.96	3.35	9.30
July-December	2,429	51.3	60.8	29.9	18.33	5.04	10.24
1988							
January-June	2,481	51.9	59.8	28.4	19.37	5.16	10.87
July-December	2,488	53.0	60.4	30.7	20.06	5.84	11.48

1 Between January 1979 and December 1981 noninterchangeable drugs are grouped with interchangeable drugs; from January 1982 they are grouped with single-source drugs.

2 A separate drug product is defined as one having a unique drug identification number (DIN). A separate DIN is given for each different dosage form and strength of a drug; and, for a given dosage form and strength, a different DIN is used for each brand for each manufacturer.

Source: Ontario Ministry of Health, "Manufacturers profile system, ODB report 2 – Drug cost report, summary of market activity," Tables 4.iv, 5*a* to 5*d*.

> Fifty-seven drugs on the top 200 list during the first six months of 1988 were not among the top 200 during the same period in 1985. These 57 drugs involved materials costs of $3.54 million and accounted for 22 per cent of all materials on the list [New Brunswick Commission on Selected Health Care Programs 1989, 16].

This instability among the leading drugs is also evident in Saskatchewan. There the plan extends to those eligible in the whole population, so the data offer a more complete picture of product turnover, where

> Almost half of all 1985/86 expenditures were for new products. Some of this represented new strengths and forms of active ingredients that were available in 1977/78, but the majority simply represented completely brand new products [Saskatchewan Review Committee to the Minister of Health 1989, 18].

Table 7-2

The status of the 32 highest-dollar-volume drugs,[1] Ontario Drug Benefit, March 1979 and 1989

Drug, strength, and dosage form[3]	Sales rank, March 1989	Eligible benefit, 1979	Market share, 1989[2]	Interchangeable 1979	Interchangeable 1989
			(Per cent)		
ranitidine HCl 150-mg tablet	1	no	4.98	...	yes
diltiazem HCl 60-mg tablet	2	no	2.26	...	yes
captopril 25-mg tablet	3	no	1.95	...	no
salbutamol inh. 200-dose package	4	yes	1.71	no	no
diltiazem HCl 30-mg tablet	5	no	1.52	...	yes
nifedipine 20-mg LA tablet	6	no	1.26	...	no
diclofenac sodium 50-mg ent. tablet	7	no	1.24	...	no
nifedipine 10-mg capsule	8	no	1.18	...	yes
diclofenac sodium 100-mg LA tablet	9	no	1.18	...	no
glyburide 5-mg tablet	10	yes	1.05	yes	yes
triazolam 0.25-mg tablet	11	no	1.05	...	yes
amiloride HCl and hydrochlorothiazide 5-mg and 50-mg tablet	12	no	0.99	...	no
potassium chloride 8 mEq LA tablet	13	yes	0.97	no	no
digoxin 0.125-mg tablet	14	yes	0.97	no	no
atenolol 50-mg tablet	15	no	0.92	...	yes
acetaminophen compound with codeine 30-mg tablet	16	yes	0.86	yes	yes
sucralfate 1-g tablet	17	no	0.75	...	no
verapamil HCl 80-mg tablet	18	no	0.74	...	no
hydrochlorothiazide and triamterene 25-mg and 50-mg tablet	19	yes	0.74	no	yes
enalapril maleate 5-mg tablet	20	no	0.72	...	no
captopril 50-mg tablet	21	no	0.71	...	no
domperidone 10-mg tablet	22	no	0.68	...	no
acetylsalicylic acid 650-mg ent. tablet	23	yes	0.66	yes	yes
furosemide 40-mg tablet	24	yes	0.65	yes	yes
timolol maleate 0.25% oph. sol.	25	no	0.65	...	yes
pentoxifylline 400-mg LA tablet	26	no	0.65	...	no
acetylsalicylic acid 325-mg ent. tablet	27	yes	0.63	yes	yes
acetaminophen compound with codeine 15-mg tablet	28	yes	0.61	yes	yes
famotidine 40-mg tablet	29	no	0.60	...	no
psyllium mucilloid oral pd. 340-g package	30	yes	0.55	yes	yes
beclomethasone dipropionate aero. pd. 200-dose package	31	yes	0.54	yes	yes
lorazepam 1-mg tablet	32	yes	0.53	no	yes
Total	...	...	34.49	...	...

1 The sample consisted of the 32 drugs that had the highest dollar volume in March 1989.
2 Of total ODB expenditure on drugs, including dispensing fees.
3 All brands of a given drug dosage form and strength are combined for the purposes of this table.
SOURCE Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989; and Ontario Ministry of Health [1979a, 1989a].

A Comparison of Old and New Drug Prices

Newer drugs tend to be more expensive than the drugs that they replace or the average price of existing drugs. In order to compare the prices of old and new drugs, we present information about drugs listed in the Ontario formulary in the period 1979-88 (Table 7-1). For this exercise the price of a new drug was proxied by a single-source drug; that of an older drug by an interchangeable drug. The prices compared were the drug costs per ODB claim. Thus a weighted average of single-source and interchangeable drug claims is employed. The difference between the prices of

old and new drugs appears to have widened since 1979. The prices of new drugs were, on average, 84 per cent higher than those of older drugs in the first half of 1979; in the same period in 1988 they were 275 per cent higher.

The Influence of Cost on Drug and Brand Choice

Making cost-effective prescribing decisions under these dynamic marketplace conditions is not an easy task for the individual physician. However, when set in the context of the drug delivery system and the incentives it creates, the outcome is a set of forces that are likely to impede rather than enhance cost-effective prescribing.

For most goods and services – for example, bread, movies, or automobiles – the person who demands, consumes, and pays for the commodity is the one and the same. Not so for drugs: the demander is the physician, the consumer is the patient/consumer, and the payer is the provincial government or a third-party drug plan.

It is assumed that the patient/consumer lacks the medical expertise to diagnose an illness and make decisions as to the appropriate course of treatment in the light of the costs and benefits of each. Instead, these decisions are, to a considerable extent, delegated to the physician, who also acts on behalf of the provincial government (or a third-party drug plan) to ensure the most cost-effective treatment.

Cost is unlikely to be a major factor for two out of these three participants. The physician's primary concern is with the physical and mental well-being of the patient. Since drugs are provided free of charge for those covered by the ODB, and the average patient/consumer copayment under Green Shield and Blue Cross is low (49.5¢ and $1.59 per prescription, respectively, in 1988 [Hurley 1989, 30-32]), the price of the drug is unlikely to enter into the calculus of patient/consumer well-being for a very large percentage of prescriptions written in Ontario.[3]

There are other reasons, however, why cost may only play a minor role in the physician's choice of drug. Determining the most cost-effective strategy requires time on the part of the physician, particularly in view of the dynamic nature of the drug market. One of the ways in which governments have sought to reduce or contain health-care expenditure has been to limit fee increases for the various procedures and operations that physicians perform. Since physicians receive most of their remuneration on a fee-for-service basis [Williams and Cockerill 1989, 13], an incentive is created for physicians to increase the number of billable procedures in order to maintain their income. Since more cost-effective drug prescribing is not a billable procedure, there is no direct financial incentive for physicians to provide such services. Indeed, it has been argued that prescribing is a strategy employed by physicians with high-volume practices to terminate a visit by the patient/consumer [Soumerai et al. 1989, 270].

The incentive structure created by the separation of cost considerations from the prescribing decision probably means less than optimal cost-effective prescribing. This is reinforced by the promotional activities of the large multinational drug firms that dominate the prescription drug industry in terms of their size and the scale of their new product introductions. In the late 1980s these firms together spent, on average, between $6,500 and $10,000 annually per physician in promotional activities aimed at ensuring that physicians prescribe their new drug products [Pharmaceutical Inquiry of Ontario 1990*a*, 102], much of it targeted at physicians who prescribe in high volumes.[4] Such promotional activities include employing detail persons to visit physicians and distribute free samples, conducting direct mail campaigns, and placing advertisements in medical journals.

Brand-name drug manufacturers have little interest or incentive to supply information on drug costs or equivalence, because physicians are usually more concerned about whether a new drug offers a therapeutic advantage over existing drugs than whether it is less expensive. Nor do brand-name drug firms have any incentive to provide data certifying that two brands of a drug are therapeutically equivalent (interchangeable). In fact, brand-name firms that introduce new products are precisely the firms that are likely to lose market share and profits when a cheaper generic brand comes onto the market – as demonstrated in Chapter 5. If anything, the owner of the original patent and brand has the incentive to suggest that there are differences between the generic brand and the originator's brand, and that the originator's brand should be prescribed and dispensed (see Chapter 6).

In sum, only the payer has a strong incentive to promote cost-effective prescribing, but its payments are to a very large extent determined by the physician and the patient/consumer, for whom cost matters little.

The discussion so far suggests that there are good reasons to believe that cost-effective prescribing is not the norm. This is contrary to the assertion by the Pharmaceutical Inquiry of Ontario that "Ontarians generally receive excellent treatment involving prescription drugs. For the most part, pharmaceutical products are safe, effective and appropriately prescribed, dispensed and used" [1990*a*, i].

If cost-effective prescribing were the norm, one would expect physicians to be aware of drug prices and the costs and benefits of different treatments for the same condition. Furthermore, the primary source of information for prescribing would be the scientific literature rather than drug company representatives. On both counts the evidence is inconsistent with these expectations. In a recent survey of physicians in Ontario, Williams and Cockerill addressed medical education and professional development. They found that although physicians were satisfied with their medical education, they were "less satisfied with their knowledge in the areas related to prescribing, suggesting the limits of conventional medical education in a field which is constantly and rapidly changing." More specifically, they report that:

> While six in ten physicians are satisfied with their ability to judge drug effectiveness, less than a third are satisfied with their knowledge of equivalencies of similar drugs, equivalencies of different brands of a drug, and non-drug alternatives. Less than a fifth of all physicians are satisfied with their knowledge of drug costs. These findings suggest that prescribing decisions will tend to be made within a limited range of information about the effectiveness of drugs which physicians are already familiar with, thus reducing or precluding the possibility that more cost-effective or non-pharmacological alternatives will be utilized [1989, v].

In view of the Ontario government's attempt over the past 20 years to provide information about these issues, especially about equivalencies of different brands of drugs and drug costs, this is a somewhat surprising finding.

On physicians' sources of information, the study reports that:

> The average physician attends roughly twice as many industry-sponsored seminars about prescription drugs as seminars sponsored by the profession and has extensive contacts with the industry through "detail men" whose primary function, as the title suggests, is to provide physicians with details of the products their companies market in order to increase the sales of those products. Even though physicians tend to rate industry contacts as relatively unimportant sources of information in their practices, the sheer volume of such contacts may nevertheless ensure that they have an impact on prescribing. High volume prescribers report significantly more frequent contacts with the pharmaceutical industry.
>
> The apparently greater attractiveness of industry-related events and contacts may be in part related to the range of "perks" offered to physicians. Majorities of Ontario physicians report that they receive meals and stationery from industry sources. Small numbers report the receipt of more significant benefits including conference fees, travel expenses and computer hardware and software. Frequency of industry contacts, range of benefits received and prescription volume are positively intercorrelated [1989, vi-vii].

While the survey affirms the importance of drug industry representations, it suggests, paradoxically in view of drug firms' promotional outlays, that this is a relatively unimportant source of information.

Avorn et al. investigated the relative importance of various sources of information in physicians' decisions to prescribe a specific set of drugs. In their study of Boston-area physicians, they selected a set of drugs for which "commercial 'channels' (advertisements, detail personnel) presented a message of efficacy and reliability, whereas scientific channels (published reports of clinical trials or review articles) presented a message of minimal efficacy or total uselessness" [1982, 4]. The physicians were asked to evaluate various sources of information in influencing their prescribing habits, and they were asked specific questions about the efficacy and reliability of the sample set of drugs.

The respondents ranked commercial sources low in influencing their prescribing decisions, and scientific channels much higher. This is consistent with Williams and Cockerill's result for Ontario. However, the physicians' views about the efficacy and reliability of the sample set of drugs reflected those of the commercial rather than the scientific sources of information. The authors concluded that:

> Rather than coming as a surprise, the predominance of nonscientific rather than scientific sources of drug information is consistent with what would be predicted from communications theory and marketing research data. Drug advertisements are simply more visually arresting and conceptually accessible than are papers in the medical literature, and physicians appear to respond to this difference [Avorn et al. 1982, 8].

In terms of cost-effective prescribing, a corollary of the findings concerning physician ignorance over cost and equivalence and the influence of commercial channels on prescribing is that more expensive, newer drugs will be overprescribed relative to cheaper alternative drugs and nondrug treatments. Avorn and Soumerai [1983] investigated this possibility with respect to three drug groups: cerebral and peripheral vasodilators, an oral cephalosporin, and propoxyphere. Selected physicians were paid educational visits by clinical pharmacists in four U.S. states and given inexpensive alternatives including lower-priced drugs, no drugs, and mild exercise. The prescribing habits of the physicians were carefully monitored and compared with a control group. The results showed that there was a drop of

14 per cent in the target drugs, with no significant increase in the use of expensive substitute drugs.

In a survey of the literature on drug utilization Carruthers et al. conclude that:

> The evidence seems to be overwhelming that indeed there is a worldwide problem relating to drug utilization. It is improbable that the problem is any less in Canada. Our review of the literature clearly indicates that this problem is both serious and significant. The problem involves both overprescribing as well as inappropriate prescribing. This means that in many cases: a) the wrong drugs are prescribed; b) ineffective drugs are prescribed; c) effective drugs are not prescribed; d) drugs are prescribed in inappropriate amounts or for inappropriate periods of time; and e) expensive drugs are prescribed when less expensive or even non-prescription drugs would be as effective or more effective [1987, 242].

Other surveys, such as Soumerai et al. [1989], support these observations. The Medical Reform Group of Ontario also found, even after taking into account the paucity of information for Canada, that "it still seems clear that in a number of areas Canadian physician prescribing leaves much to be desired" [1988, 49].

On the issue of the quality of care, a recent Ontario peer assessment review program found that, of the sample of physicians studied, 15 per cent of general and family practitioners had either deficient records and/or unsatisfactory levels of patient care. Among specialists the corresponding percentage was 4 per cent [McAuley et al. 1990]. These results are consistent with a U.S. estimate that between 5 and 15 per cent of physicians may not be providing adequate care. To the extent that these physicians are disproportionately located in high-volume practices, the number of patients or share of prescriptions that they account for will be higher than 5 to 15 per cent.

Thus concern over the prescribing of more expensive drugs, when less expensive but equally effective drugs are available, is part of a wider problem of inappropriate treatment and prescribing by physicians.

Cost-Effective Prescribing: Process, Criteria, and Implementation Mechanisms

Ontario has, on paper at least, a coherent set of mechanisms and enforcement procedures designed to promote cost-effective drug prescribing. They are, by and large, aimed at rectifying the underprovision of information on price and equivalence and ensuring that ineffective drugs are not prescribed. Furthermore, a number of mechanisms have been introduced to ensure some compliance with the cost-effective prescribing recommendations implicit in the information provided.

The Process

The process by which a drug becomes listed as an eligible benefit under the 1986 Ontario Drug Benefit Act and certified as interchangeable under the Prescription Drug Cost Regulation Act is outlined in Figure 7-1. There are four stages: submission of the drug, testing and review, evaluation, and implementation. Various regulations and administrative guidelines govern this procedure. Manufacturers, the Drug Quality and Therapeutics Committee (DQTC), the Ministry of Health, and the cabinet are all involved. Attention is confined here mainly to the DQTC.

The Drug Quality and Therapeutics Committee

The DQTC is pivotal in the drug submission process. The chairman, the vice-chairman, and all the members of the committee are appointed by the government. In early 1991 there were 19 people on the committee, largely expert medical professionals such as physicians, pharmacists, and specialists from other relevant disciplines, both practising and in universities.[5]

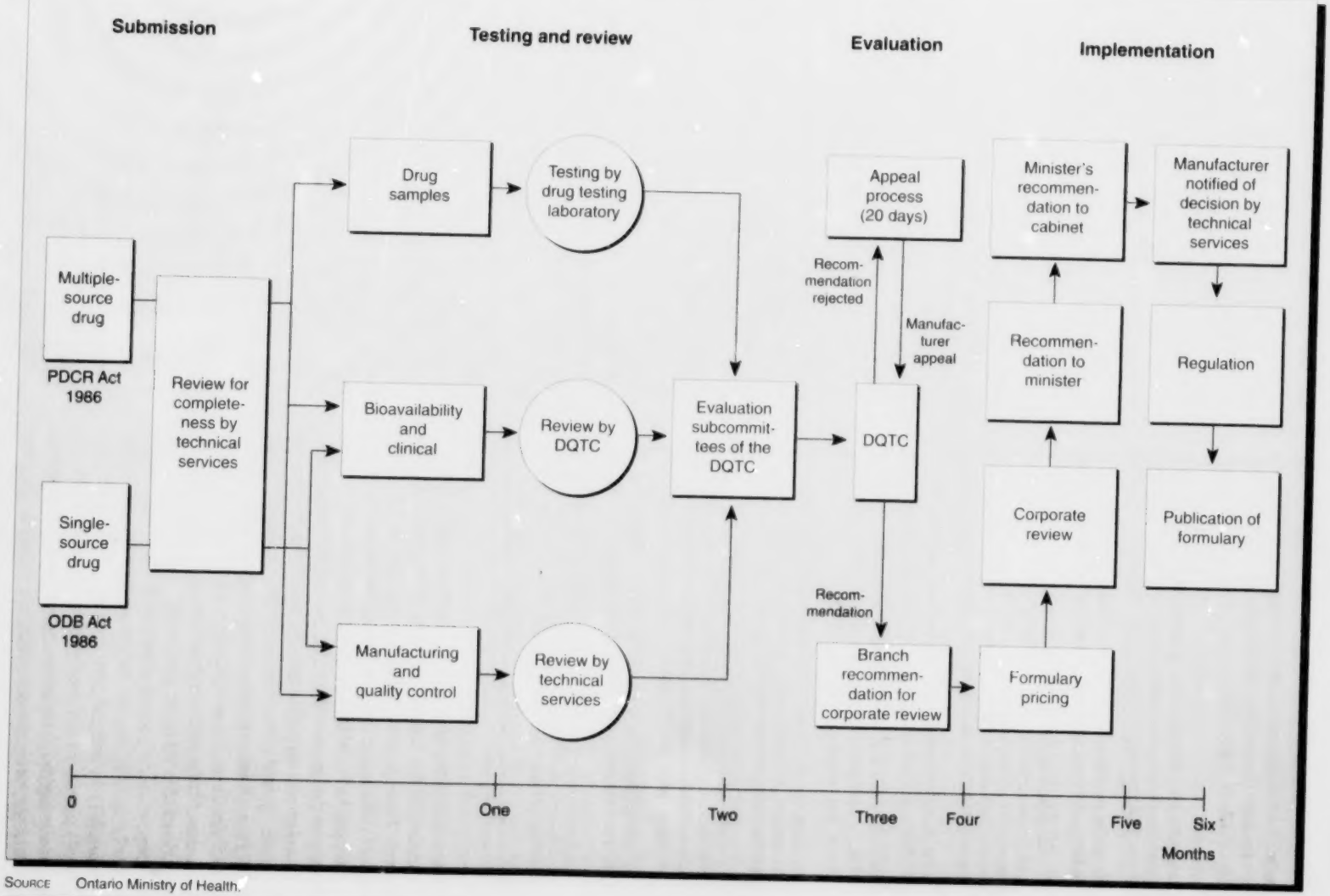
The terms of reference of the committee are reproduced on page 114. They are wide ranging, and promoting cost-effective drug prescribing is clearly a central part of the committee's mandate. The first item calls for the DQTC to advise the Minister of Health on obtaining prescribed drugs of quality at reasonable cost; item three refers to interchangeability, a major method of promoting cost-effective drug therapy; while item six provides the DQTC with a limited opportunity to communicate its recommendations to health professionals and others.

Timing and Volume

At present the drug submission procedure takes six months to coincide with the January and July editions of the formulary (occasionally the deadlines are extended). Before considering submissions for each formulary, letters specifying the deadlines for submission are sent to the manufacturers. This procedure is likely to change in the near future; in 1991 the Ministry of Health put forward proposals (on the recommendation of the Pharmaceutical Inquiry of Ontario [1990*a*, 40-41]) to institute a continuous drug submission review and publish the formulary annually with updates as products are added or deleted. Price increases would be annual, not semi-annual as they are at present.

Figure 7-1

The drug submission process for inclusion in the Ontario formulary



SOURCE Ontario Ministry of Health.

Terms of reference of the Drug Quality and Therapeutics Committee, revised in OC 1035/90, 20 April 1990

1 To advise the Minister on the operation of a program to assist the people of Ontario to obtain prescribed pharmaceutical products of quality at reasonable cost.

2 To establish, maintain, and apply criteria to evaluate the quality and therapeutic value and cost of drug products.

3 To recommend to the Minister which drug products have met the prescribed conditions to be eligible to be designated as interchangeable products or listed drug products for the purposes of the Prescription Drug Cost Regulation Act, 1986 and the Ontario Drug Benefit Act, 1986.

4 To evaluate pharmaceutical manufacturers' facilities and products.

5 To monitor and evaluate, on a continuous basis, the list of drugs available in the light of drug use patterns, experience, and current scientific knowledge.

6 To recommend for distribution to the public and the health professions, information relating to drugs, pharmaceutical products, and therapeutic topics.

7 To review and assess information related to drugs and pharmaceutical products prepared for the Committee and for the Minister by selected consultants from time to time as requested by the Minister.

8 At the Minister's request to act as liaison between the Minister and professional, educational, and other groups.

9 To provide advice on relevant drug, pharmaceutical and therapeutic questions solicited or requested by the Ministry of Health from time to time.

In Table 7-3 the volume of drug products considered for and included in the January and July 1989 formularies is presented. There is probably an upward bias in the numbers, since different strengths of a drug are counted as separate drug products. With this caveat in mind, two conclusions can be drawn from the table: the DQTC considers a large number of drug products, and a nontrivial percentage of them are rejected – 14.1 per cent for January and 27.8 per cent for July. (A fuller picture of the number of drug products included in each formulary between 1979 and 1988 and the net change in the number between formularies is provided in Table 7-1.)

Procedures

In submitting drugs for inclusion as eligible benefits in the formulary, drug manufacturers are asked to provide documentation for each drug, including the Notice of Compliance, the product monograph, the drug identification number, the ingredients, a description of the quality control procedures employed, clinical studies, and so on. Firms submitting a drug seeking to become interchangeable with the original product must submit comparative bioavailability studies and/or comparative clinical studies in humans or other in vivo studies that will demonstrate interchangeability. In the case of a single-source product, where relevant, evidence on the need for an additional strength or modified-release dosage form is required.

The next step in the drug submission procedure is testing and review, which involves the Technical Services Branch of the Ministry of Health as well as the DQTC. The ministry examines the drug samples provided by the manufacturer and the manufacturing and quality control procedures. A member of the DQTC (or sometimes an outside expert) evaluates the bioavailability and clinical data. On the basis of all this evidence, a recommendation to a subcommittee of the DQTC is made as to whether or not the drug product should be listed in the formulary. This subcommittee's recommendation then goes to the DQTC as a whole, which, in turn, makes a final recommendation to the Ministry of Health.

In the vast majority of cases the DQTC's recommendation is accepted by the minister. The manufacturer is notified of the DQTC's recommendation and the ministry's concurrence. If a drug is rejected, the reasons are provided in notifying the manufacturer. These could be that there is inadequate documentation with respect to therapeutic

Table 7-3

Number of drug products[1] considered by the DQTC for inclusion in the formulary, Ontario, 1989

	For formulary in	
	January 1989	July 1989
Reviewed	78	54
Approved	67	39
Interchangeable[2]	38	11
Single source	29	23
Rejected	11	15
Interchangeable	0	0
Single source	11	15

1 A drug product is defined as having a separate DIN.
2 Noninterchangeable and interchangeable drug products.
Source Based on data from the Ontario Ministry of Health.

effectiveness, that the product is not superior to existing products yet is twice as high in price, and so on. There is an appeal process. The manufacturer can, for example, provide additional evidence to substantiate a claim. The response is then forwarded through the ministry to the DQTC to reconsider its decision.

Implementation

The final stage of the drug submission process is implementation. Once the ministry has accepted the DQTC's recommendation and any appeal has been dealt with, the ministry has to decide on the price of the drug for reimbursement purposes – the BAP. All the relevant documentary support for the recommendations of both the DQTC and senior officials of the ministry are then sent to the minister and eventually to the cabinet. However, only in cases which are likely to attract public attention or involve particularly important public policy issues do the minister or the cabinet become actively involve. The cabinet's involvement reflects the fact that the formulary is published pursuant to the power vested in the Lieutenant Governor in Council under the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act. The final stage in the drug submission process is the publication of the formulary, which is distributed free to medical practitioners, pharmacies, and hospitals in Ontario. Mechanisms are in place for the ODB to reimburse for drugs that are not included in the formulary. These are referred to as nonformulary benefits, formerly special authorizations, and are discussed below.

The drug submission process does not always proceed in the fashion described above. If a firm fails to get its product listed as an eligible benefit in the formulary, it may challenge the decision in court, appeal to the Minister of Health, or even lobby the cabinet. Apotex, for example, has engaged in several of these avenues of appeal. In 1980, when its attempt to get Apo-Propranolol listed as interchangeable was rejected by the DQTC, the company appealed to the Minister of Health, who set in motion a review procedure that led to the reversal of the DQTC's decision. Four years later the ministry refused to list the company's brand of ibuprofen 600-mg tablets as interchangeable because Apotex had not complied with the ministry's submission deadlines. However, when the company learned that Kenral's brand had also missed the deadline but had been listed, it went to court and was successful in reversing the ministry's decision.[6] However, in other instances, Apotex was unsuccessful in altering or varying the ministry's decisions.[7]

Sometimes other actors become involved in the process. For example, if a generic firm such as Apotex or Novopharm makes a submission for its brand to become interchangeable with the original or brand-name product, the manufacturer of the brand-name product may seek to intervene to prevent, slow, or alter the outcome of the drug submission process. For example, it might launch a legal action alleging that the conditions for interchangeability have not been met, or it might quietly lobby officials and cabinet ministers [Pharmaceutical Inquiry of Ontario, 1990*a*, 60-61]. The latter is what happened when Apotex applied to have Apo-Salvent made interchangeable with Ventolin for the inhalator 200-dose package (see box on page 116 for further details of this case).

The Criteria

In this section the various criteria for inclusion in both the legislation and official or quasi-legal rules are described.

Legislative Rules

There are no specific guidelines in the Ontario Drug Benefit Act as to the criteria to be employed in listing drugs in the formulary. Nor does the Prescription Drug Regulation Act specify criteria for the listing of a product as interchangeable, except that it must contain "a drug or drugs in the same amounts of the same active ingredients in the same dosage form as the other product" (Section 14 (1)(b)(i)). Detailed requirements are left to the discretion of the Lieutenant Governor in Council (see Ontario Drug Benefit Act, Sections 18 (b) and (c) and the Prescription Drug Cost Regulation Act, Sections 14 (1)(a) and (b)). These requirements are set out in the regulations passed pursuant to these two acts. They detail the documentation that is required when a manufacturer submits a drug for consideration as an eligible benefit.

The criteria for accepting or rejecting a manufacturer's submission are not set out in legislation or regulations, beyond the fact that the application must be completed in accordance with the regulations relating to the drug submission procedure. In other words, there are, in the legislation and associated regulations, a necessary (but not sufficient) set of conditions for becoming an eligible benefit. Thus, even if these necessary conditions are satisfied, the Lieutenant Governor in Council may reject the submission when he/she "considers it advisable in the public interest to do so" (Ontario Drug Benefit Act, Section 18 (1)(c); Prescription Drug Cost Regulation Act, Section 14 (1)(b)). In the case of Ventolin, described above, the Lieutenant Governor in Council could simply have said no without giving any reasons, despite the DQTC's unanimous recommendation

Listing a drug in the Ontario formulary: the case of Apo-Salvent

Glaxo Canada Inc., the manufacturer of Ventolin, indicated that a favourable decision on interchangeability for Apo-Salvent could jeopardize its future research and development in Ontario and demanded that Apo-Salvent be sent back to the DQTC for reconsideration. Although the cabinet agreed to this request, the DQTC did not change its recommendation, and the cabinet affirmed the recommendation in the July 1989 Ontario formulary. At face value it would appear that the intervention by Glaxo was unsuccessful, in that Apo-Salvent was listed as an eligible benefit and interchangeable and not delayed until the January 1990 formulary or listed as an eligible benefit but as noninterchangeable. Glaxo's intervention, however, was not without effect on the drug submission process. The fact that the cabinet sent Apo-Salvent back to the DQTC for a second time undermines its judgment and authority. The media coverage meant that some doubt was probably sown in the minds of at least some physicians and may have led to a greater number of no-substitution prescriptions for Glaxo's brand when the generic brand appeared. It may even have led concerned ODB recipients to request no-substitution prescriptions for Ventolin. Finally, the formulary became effective on 17 July rather than 1 July. This meant that the January 1989 formulary was in effect for the first 17 days of July 1989 with Glaxo's brand listed as a single-source drug. This probably meant hundreds of thousands of dollars worth of sales to Glaxo, but other drug firms may have been adversely affected because the revenue from higher prices may have had to be forgone. These results could well persuade other manufacturers of an original product to lobby in a similar manner when a generic firm applies to have its product listed as interchangeable. If there was enough of a concerted effort by a number of original product owners this *might* mean a formulary would be issued without the interchangeable brands listed and thus confer a substantial benefit to the patent owner for six months or perhaps longer. Such uncertainty would, of course, add considerably to the costs of the generic manufacturer in terms of increased inventories, idle machinery, delayed advertising, and so on. The original product manufacturer might also experience increased costs as a result of the uncertainty about decisions such as whether or not to launch a fighting brand, the nature of future advertising, and the appropriate level of output.

Based on a series of articles by Janice Turner in the *Toronto Star* in June and July 1989, and interviews.

to list Apo-Salvent, but this might, of course, have resulted in resignations from the committee.

Official Rules

Although there are no sufficient conditions for a drug to be listed as an eligible benefit, five criteria that could be interpreted as promoting cost-effective prescribing are listed in the formulary, under the heading "Selection of drugs" (see box below). Since the formulary is published pursuant to a regulation of the Lieutenant Governor in Council, these criteria clearly have some official standing. The first, for example, states that where there are zero benefits and the drug has a positive price, it should not be included, while the fifth carefully lists the medical cost as well as considerations that should be satisfied before combination products (two or more drugs combined to make one) are included in the formulary.

Overview

The system of encouraging cost-effective prescribing is designed to provide data on prices and quality that the market, left to itself, is unlikely to provide in a credible manner. The assignment of different tasks to the various participants in the drug delivery system seems to be effective and to use resources in an efficient manner. Assessing

Selection criteria for inclusion of drugs in the Ontario formulary

1 The proven medical value of the drug for the diagnosis, prevention, or treatment of mental or physical disorders.

2 The balance between therapeutic usefulness and potential harmful effects, and the availability of suitable alternative agents.

3 Patient well-being or therapeutic outcome is not compromised by interchanging pharmaceutical products.

4 A higher-priced analog is included if it offers a therapeutic advantage.

5 Combination products are included if, in addition to meeting all other criteria:

   i) each component of the combination makes a contribution to the claimed effect, and

   ii) there is a pharmacological and pharmaceutical rationale for the mixture; the effect of each component should extend throughout the recommended dosage interval of the combination, and

   iii) the dosage of each component (amount, frequency, duration) must be such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labelling for the drug, and

   iv) where the cost is comparable to that of similar medication prescribed as one or more single entities.

From Ontario Ministry of Health [1989a, ix]; see also p. vii.

information concerning the therapeutic equivalence of two brands of the same drug is probably better done by the DQTC than by individual physicians who have neither the time nor the incentive. Equally, evaluating the scientific literature on a drug to determine its effectiveness in various uses and the quality of the manufacturing facilities is best left to a central body. Where interchangeability is certified, it seems sensible to let the marketplace determine brand choice and price.

Nevertheless, procedures and mechanisms currently in place to promote cost-effective prescribing do not exhaust the full range of possible instruments open to government, nor do they address all the causes of less than optimal cost-effective prescribing. For example, there is no attempt to encourage the use of less expensive drugs or treatments, and little or no attempt is currently made to ascertain systematically whether a new drug offers benefits commensurate with its costs. No criteria are stated for delisting a drug, and physicians' prescribing behaviour is not monitored.

Administrative Matters: the Role and Responsibilities of the DQTC

The DQTC plays a pivotal role in the drug system in Ontario, not only with respect to quality assurance but also in terms of controlling drug costs. Its recommendations are of considerable economic and medical importance and are frequently difficult, with the professionals putting their reputations on the line. The committee should therefore meet certain administrative criteria and conditions in fulfilling its mandate, so as to ensure maximum effectiveness. The drug submission process should be and seen to be procedurally fair. That is to say, the participants in the process – mainly manufacturers (but also the Ministry of Health) – should regard the procedure and machinery as impartial, and the DQTC's decisions should be reasoned, sensible, and in accordance with publicly known criteria. The process should also be timely. If it is inordinately long, not only is the public denied the benefits of new drugs and lower-priced generic brands, but manufacturers experience forgone sales because of the delay. Finally, the procedures and administration should be such that health practitioners have confidence in them.

Procedural Fairness and Timeliness

The objectives of fairness and timeliness may conflict. A drug may be listed relatively quickly but without proper evaluation and time for manufacturers' appeal. On the other hand, a lengthy process of approval, with a formal notice and comment period during which a wide variety of parties can participate, may considerably slow down the rate of new listings in the formulary. Among six U.S. states that had formularies for a significant period, in 1982 the lag between marketing a new drug (within the United States) and gaining formulary approval for Medicaid varied between 40 months in California to 10 months in South Carolina [Grabowski 1988, Exhibit 1, 104].

The procedure employed in Ontario seems a sensible compromise between speed and fairness. Relative informality seems much more appropriate – if it works – than formality with its attendant costs and delays. Nevertheless, there is room for improvement in the current system. Guidelines and procedures should be developed with respect to intervention by parties not directly involved in an application for listing in the formulary. For example, if firm A asks for product X to be listed as interchangeable with firm B's brand-name product, the latter may decide to intervene. There are no procedures in place for such intervention. Nevertheless, a paragraph in the 24 May 1990 letter sent to drug manufacturers concerning the January 1991 formulary listings states: "Please note that any information provided by a manufacturer regarding a competitor's product may, at the discretion of the Ministry, be shared in whole or in part with that competitor, except for proprietary information." Thus the process is gradually moving in the right direction.[8]

Procedural Safeguards

The DQTC makes recommendations involving millions, indeed tens of millions of dollars. Thus there is a special onus on the DQTC to be seen to be beyond reproach and to avoid situations like those in the early 1980s, when members of the committee participated in decisions about listing a firm's drug products as interchangeable for which they had formerly been consultants [Apotex 1988].

The following measures might enhance the respect for and prestige of the DQTC's decisions:

- Introduce stricter guidelines concerning conflict of interest, security, and confidentiality.[9] One model would be that for the proposed federal Advisory Panel on Biopharmaceutics and Pharmacokinetics.[10]

- On general issues such as moving from a biannual to a continuous formulary, or the interchangeability of long-acting dosage forms, ask for briefs and perhaps hold meetings before issuing recommendations (which would be made public).

- Where possible, classify the reasons for not listing a drug in the formulary; these should be communicated to

drug manufacturers when requesting submissions to the formulary.

Criteria for Cabinet Intervention

The cabinet has absolute discretion in approving or disapproving a drug for listing in the formulary, irrespective of the recommendation of the DQTC.[11] There are, however, no established guidelines or criteria for the cabinet to base its decisions on. This encourages the sort of lobbying that has been undertaken by drug companies in the past.

If the decisions of the DQTC are not accepted by cabinet, this is likely to undermine the credibility of the committee, frustrate its members, and perhaps reduce the supply of those willing to be appointed. Although the DQTC's recommendations are usually followed, several steps could be taken to maintain and strengthen its credibility:

- The cabinet (or the Ministry of Health) could articulate and make public the reasons why a DQTC's recommendation is rejected or varied.

- The cabinet's role could be restricted to proclaiming broad policy guidelines, as the legislation provides for them, leaving the DQTC to administer them. The cabinet would step in only if the guidelines are not followed.

Such procedural safeguards would maintain the credibility of the DQTC and shield the cabinet from pressure by interest groups.

Communicating with Its Public

The DQTC makes recommendations about several issues in addition to interchangeability. Yet it has no way of communicating its recommendations to health professionals. Indeed, one of the reasons that the former chairman of the committee resigned was because of "the lack of an effective communication and information system between the DQTC, the prescriber and public." The formulary committee in Saskatchewan issues a bulletin.

A newsletter accompanying each formulary could explain the DQTC's decisions. It could also be a forum in which physicians' and pharmacists' concerns about drug therapy and cost could be raised and discussed. The DQTC could also use the newsletter to identify potential problems in prescribing; for example, it could inform prescribers about cheaper alternatives to widely prescribed, expensive drugs and about drugs that are deemed less effective by the medical literature.[12] The existing monthly reports on ODB drug utilization could be carefully monitored to evaluate the effectiveness of such strategies.[13]

These proposals are consistent with the general tenor of a report prepared for the cabinet, which favours agencies that are "accessible, efficient and responsive to the competing needs of individual rights and the public interest" [Macaulay 1989, 1-2),[14] and the suggestions of the former chairman of the DQTC, Dr. Carruthers. To the extent that they clarify the DQTC's procedures and decision making to drug manufacturers, they should result in fewer resources being devoted to the drug submission process.

How the Leaky Boat Finally Sank: Special Authorizations

One way that cost-effective prescribing is promoted is through the exclusion from the formulary of products that are not of acceptable quality or offer little advantage over existing therapies but cost substantially more. This is stated explicitly both in the DQTC's terms of reference (see box on page 114) and in the formulary (see box on page 116). It has been a constant theme of government intervention in the Ontario drug market (see Chapter 3).

Until recently, drugs that were not listed in the formulary got what were known as special authorizations, and these drugs were listed on a special authorization list. The procedure was recently changed; these drugs are now called nonformulary benefits. In this section the old system will be evaluated and the reforms will be described.

One indicator of the success or confidence practitioners have in the ability of the formulary to meet the quality assurance objective is the extent that nonformulary drugs, i.e., special authorization drugs, are prescribed under the ODB. Special authorizations were originally intended to be used "in rare instances where drug products not listed in the Ontario Drug Benefit Formulary were considered necessary for the care of a particular eligible patient" [Pharmaceutical Inquiry of Ontario 1988*b*, i]. However, the program grew substantially once the ODB was extended to cover all those aged 65 and over. In addition, the procedure for issuing special authorization numbers – required before the Ministry of Health would reimburse for a drug – was changed, making them much easier to obtain.[15] By the late 1980s it had stabilized. In March of each year between 1986 and 1989 special authorizations accounted for about one in every 50 drug claims and about $1 in every $25 spent by ODB on all drug claims (Table 7-4). In 1988 total ODB expenditure on special authorizations was about

Table 7-4

Special authorizations[1] as a proportion of the number and value of all claims paid for by the Ontario Drug Benefit, 1986-89[2]

	Special authorizations as a proportion of all ODB	
	Claims	Value[3]
	(Per cent)	
1986	2.4	4.8
1987	1.7	3.3
1988	2.4	4.2
1989	2.4	4.2

1 The table refers to drugs only, and hence excludes oxygen and allergens.
2 In March of each year.
3 Drug cost and dispensing fee.
Source Ontario Drug Benefit, "Formulary utilization," computer printouts, March 1986-89.

$25 million. To look at it another way, in July 1988 there were nearly 2,500 drug products listed in the formulary, and 1,600 on the special authorization list. Some of these drug products accounted for not insubstantial amounts of money – ODB expenditure on five special authorizations exceeded $1 million in 1988. In the words of the Pharmaceutical Inquiry of Ontario, this list had become a second "mini-formulary [1988*b*, 8]. Such numbers would suggest that the use of special authorizations could no longer be described as rare.

According to Dr. Carruthers, the former chairman of the DQTC, drugs that are ineffective are included on the special authorization list [McLaren 1988]. An examination of how the leading special authorization drugs are viewed in the scientific literature confirmed his view. In 1986 these drugs (defined as those whose annual ODB claims volume was approximately $250,000) were the following: Persantine, $3.9 million; Nitrong SR, $1.1 million; Vitamin E, $0.7 million; Hydergine, $0.5 million; Motilium, $0.3 million; and Arlidin, $0.2 million.[16]

According to the American Medical Association several of these drugs do not receive top marks. For Persantine, the drug with the highest dollar volume in the sample, it says the following: "Efficacy has not been established; therefore, no dosage is suggested" [1986, 478]; for Arlidin, it says: "Because the role of this agent in the treatment of peripheral vascular disease has not been established, no dosage is suggested" [493]; and while a number of uses are discussed for vitamin E, it concludes: "There is no evidence to support the efficacy of vitamin E in the numerous conditions in which it is popularly used" [849]. For Nitrong and Hydergine there appears to be no listing, and Motilium was clearly the drug of choice in certain circumstances [264-65]. (It was probably on the special authorization list because it was in the process of entering the formulary, which it did in December 1986.) These results confirm the view of Dr. Carruthers that: "The absurd Special Authorization system . . . squanders millions of dollars annually, in large part for drugs which have little or no proven therapeutic value" [1988].

Assessment

Although the idea of special authorizations was sound in practice, the lack of a rational policy underlying the special authorization process made its implementation somewhat of a sham. There were no proper administrative checks. It undermined both the legitimacy of the DQTC, the government's own cost control mechanisms, and the principle of interchangeability.

Reforming Special Authorizations: Nonformulary Benefits

In the first quarter of 1989 the Ontario Ministry of Health moved to reform the special authorization system, on the recommendation of the Pharmaceutical Inquiry of Ontario [1988*b*]. Special authorizations became nonformulary benefits, and the list was issued as an insert with the formulary rather than being part of it.

The criteria for inclusion on the nonformulary benefit list were tightened considerably. Drug products which had not been reviewed by the DQTC, and for which there was insufficient or unsatisfactory information concerning efficacy, but for which alternatives existed, were excluded from the list. Drug products that had previously been excluded from the formulary were also excluded from the list unless the committee's concerns had been met. Finally, combination products not meeting the Ministry of Health criteria (see box on page 116) were also excluded. The number of drug products fell drastically, from 1,600 on the special authorization list, to a mere 200 on the nonformulary benefit list [Ontario Ministry of Health 1989*d*, 1].

The nonformulary benefit list is divided into two categories. The first one consists of limited use products that are paid for by the ODB when prescribed in accordance with specified conditions. For example, in 1989 the cost of fluoxetine HCl 20-mg capsules would only be reimbursed

when standard antidepressant therapy has been tried and failed [Ontario Ministry of Health 1989*d*, 3]. The second category consists of all remaining benefits that are either other interim benefits, nutritional supplements, or moisturizers, vehicles, and bases.[17] The DQTC has started to review all the products in these categories, a process that is still ongoing.[18]

In order for the ODB to reimburse a claim for a nonformulary benefit, a form must be completed, on which the physician states the reasons for prescribing the drug, together with the patient's ODB eligibility number. This is then presented to the pharmacist for dispensing, and a copy goes directly to the ODB.

The reform of the system led not only to a substantial decline in the number of special authorization drugs, but also to a decrease in expenditure on those products by one third between 1988 and 1989 [Pharmaceutical Inquiry of Ontario 1990*a*, 46]. Of the six leading-dollar-volume special authorization drugs listed above, only Persantine remained on the nonformulary benefit list in January 1990, and Motilium was listed in the formulary.[19]

To prescribe drugs not included on either the nonformulary benefit list or the formulary, there is a much more rigorous procedure. The physician has to present a written request for such benefits, and each request is subject to a careful medical review. The request must contain a "full account . . . of the clinical circumstances which appear to warrant coverage for the unlisted drug in a *particular patient's case*" [Ontario Ministry of Health 1990*a*, 2, emphasis in original]. These requests are considered by the DQTC.

Overall, although these reforms are sensible, they nevertheless suffer from one important omission. No attention is paid to why physicians prescribe special authorization drugs. If, as suggested earlier, physicians rely to a considerable extent on nonscientific sources of information in prescribing, will prescribing be better or worse after the removal of selected special authorization drugs? Will the substitute drugs or courses of treatment be an improvement? Will this lead to an overall increase or decrease in drug usage and program expenditure?

The impact of not reimbursing for ineffective drugs among New Jersey beneficiaries of Medicaid in the early 1980s before and after the non-reimbursement took place was examined by Soumerai et al. [1990]. The authors found that, overall, Medicaid expenditure and drug use remained unchanged, if not actually increasing somewhat. Furthermore, "both desirable and unimproved therapeutic substitutions were observed" [831]. The authors suggest that there must be some sort of physician education program as part of any elimination of drugs for reimbursement, something that could be considered in the current strategy to reform the special authorization system.

Interchangeability

One of the major policy measures designed to promote more cost-effective prescribing was interchangeability, combined with price and product selection rules (see Chapters 3, 5, and 6). Several studies have demonstrated that such policies, particularly when combined with compulsory patent licensing, have led to considerable savings, while delivering the same quality of care [Gorecki 1981, 120-49, 1986*a*; Commission of Inquiry on the Pharmaceutical Industry 1985, 311-25]. Prices fell substantially in jurisdictions that introduced such policies in comparison with those that did not. In Ontario, the savings were in the tens of millions. In this section we examine two issues with respect to interchangeability: price-setting by the ODB for the first lower-priced interchangeable brand listed, and the concerns raised by the brand-name firms and others over interchangeability.

Pricing the First Lower-Priced Interchangeable Brand

The formulary price of the first lower-priced interchangeable generic brand will fall between two extremes. Ideally, from a public policy point of view, it should be the minimum required to induce the generic firm to enter the market. This may be more than the costs of bringing the drug to market, since a reward or prize is required in order to provide an incentive for generic firms to enter the race to be the first in the market for a given drug product.

In contrast, for the profit-maximizing generic firm, the price for the first interchangeable generic brand should be as close to the brand name as possible, subject to two constraints. First, the closer the price of the generic brand is to that of the brand name, the more likely it is that the brand name will meet the price of the generic brand. Second, to the extent that the generic firms have a reputation for marketing quality products at lower prices than the brand names, pricing very close to the brand name will damage this reputation.

The listing of the first generic interchangeable brand is likely to be a decision of some significance for the ODB, particularly for the high-volume drugs that are usually tar-

geted by generic firms. A substantial price reduction below the price of the brand-name product might be a goal that the DQTC and the Ministry of Health could reasonably expect to attain.

The evidence presented in Chapter 6 indicates that the prices of the first lower-priced interchangeable brands are set by the firm. The DQTC and the Ministry of Health do not appear to negotiate or demand a substantial price reduction [see also Archer 1991, 110]. For fighting brands, where the interests of the firm marketing the brand are in a high not a low price, the ministry could seek a somewhat greater discount than 0 to 5 per cent that these brands offer when they enter the formulary and there is no generic competition. However, the discount should not be too great, or the fighting brand may not enter, or if it does enter, this may discourage the generic firm.

Evaluating the Concerns about Interchangeability

Concerns about interchangeability have been raised, particularly by brand-name firms. These concerns have been disseminated through paid advertisements and promotional material. In this section these concerns and the methods by which they have been expressed are evaluated.

Since interchangeability was introduced 20 years ago in 1972, large portions of the ODB population have been shifted between two interchangeable brands of a drug of a particular dosage form and strength. In the period 1979-88 the proportion of all ODB claims accounted for by interchangeable drugs has been in the range of 57 to 70 per cent (Table 7-1). In all this time, with this extensive use of interchangeable drugs, no documented examples of patient ill health due to interchangeability have come to light in Ontario. A similar finding holds for the United States [Consumer Reports 1987, 481].

The province accepts liability for interchangeability whether or not the person is covered by the ODB. Another indication of the success of interchangeability is the fact that the province has not paid any damages resulting from this liability. The lack of problems with interchangeability is like the dog that did not bark in a Sherlock Holmes story. It leads to the question of how valid the concerns of brand-name firms are, and how much merit to give their questioning of decisions by the DQTC and the Ministry of Health regarding interchangeability.

Although the briefs presented by brand-name firms to the Pharmaceutical Inquiry of Ontario and the federal Commission of Inquiry on the Pharmaceutical Industry make suggestions that would decrease the impact of interchangeability on their markets, they do not present any evidence that might effectively challenge the DQTC's decisions. The most obvious reason for this is that they do not possess any such evidence. Since brand-name firms certainly have the incentive to find problems with interchangeability, one must assume they have searched the literature very diligently, and perhaps even conducted studies themselves, but have not been able to find any [Merck Frosst Canada 1988, 5]. Brand-name firms have, however, presented material to physicians and pharmacists in order to encourage them to prescribe and dispense brand-name products. Why was this material presented to the Pharmaceutical Inquiry of Ontario by the generic firms [Novopharm 1988; Canadian Drug Manufacturers Association 1988; Apotex 1988] rather than brand-name firms?

The Quality of the Debate

Many of the arguments by brand-name firms and others that question interchangeability have appeared in the form of paid advertisements in the medical press and promotional material sent directly to physicians and pharmacists. Some of it could be termed alarmist in slant. A good example is the campaign by Bristol-Myers Squibb Canada before the appearance of the first two interchangeable generic brands of captopril in the February 1991 Ontario formulary. One advertisement depicts a parachute with the phrase, "Would you change parachutes in mid-descent?" in large letters above it, and across the parachute itself, "Why switch your CHF patient's therapy in mid-course?" [*Medical Post*, 29 January 1991, 13]. Another is a picture of a patient being revived in an emergency room, with the words, "If he survives this, would you really want to substitute his CHF medication?" [*Canadian Pharmaceutical Journal*, various issues]. In February 1991 the company circulated a questionnaire among pharmacists consisting of six questions. The first two were "Do you believe ALL generic products can be safely substituted, ALL the time, for ALL patients?" and "Do you think that bioavailability testing which validates similar pharmacokinetics ensures clinical/therapeutic equivalence in ALL conditions?" and the last was "Would you willingly switch an elderly congestive heart failure patient stabilized on Capoten [the brand-name product] to a generic copy?" The questionnaire was not precleared by the board that polices advertising in the drug industry, the Pharmaceutical Advertising Advisory Board. The company agreed to send a retraction letter to the same target audience of pharmacists. The parachute advertisement was withdrawn and a modified version was accepted. The emergency room advertisement is still the subject of a complaint but will have to be modified because of new information.

Some advertisements claim that there are differences between the brand-name and generic products, and that the brand name should be preferred. In one case, that of triazolam, the brand-name firm distributed in September 1989 among health professionals promotional material that included the results of a bioavailability test comparing the brand-name and the generic brand.[20] In their analysis of this material, McCormack et al. concluded that the material:

> states that "there is clearly the possibility that the observed kinetic differences between them may have clinical significance in terms of safety and efficacy." It has been shown that there is only one statistically significant pharmacokinetic difference presented and the qualified suggestion that it "may have clinical significance in terms of safety and efficacy" is very misleading [1990, 407].

The material was brought to the attention of the Pharmaceutical Advertising Advisory Board, who said that the material would not have been approved for distribution to health professionals had it been submitted for review and preclearance.

Sometimes the material is produced in video form. The Ontario Medical Association produced a 28-minute video in 1988 entitled "What did the doctor order?" that was partly funded by a brand-name firm. The purpose of the video was to inform physicians and pharmacists of the possible clinical effects of product selection and interchangeability. The Canadian Hospital Pharmacists Association commented:

> The videotape cites several anecdotal case reports where problems have been attributed to interchange of drug products. Unfortunately, the examples are not supported by scientific data or clear criteria on which to conclude that no interchange of drug products be permitted. In addition, the video presents one hypothetical case and suggests possible dangers of an anti-coagulant interchange. This example is misleading since the anticoagulants are "*not interchangeable*" in the Ontario Benefit Formulary [Giovinazzo 1988, 1-2; emphasis in original].

The head of the federal government's expert advisory committee on bioavailability, Dr. John Ruedy, commented that "the tape provides a simplistic and one-sided view on the issue of substitution . . . and an incomplete assessment of the benefits and risks of substitution" [Novopharm 1988, 9].

Certainly, in this author's view, while the video provides some discussion of the tests for bioavailability, it can hardly be regarded as a well-balanced presentation of the issue of interchangeability. No mention is made of the Ontario Medical Association's traditional support for interchangeability, the lengths that the Ontario government, through the DQTC, goes to in order to assure the success of interchangeability, or the considerable savings that have accrued to government as a result of the program.[21]

The discussion of interchangeability does raise two issues that deserve serious attention: potential problems with excipients, and the need to provide the patient/consumer with information when interchangeability takes place. These legitimate concerns should, however, be considered within the framework of a wider set of concerns.

One concern with the principle of interchangeability is that a patient/consumer who is stabilized on one brand may experience a reaction to the excipients of another brand. There are, however, many other instances where excipients may also cause problems. For example, among the 80,000 recipients for whom the ODB receives annually more than six drug claims per month, switching from one drug to another or adding a drug to the regimen is probably not an infrequent occurrence in view of the high turnover of the leading sellers and the steady increase in the number of claims per person. In addition, of course, brand-name firms sometimes reformulate their drug products. If there is a general problem with excipients – all of which have presumably received regulatory approval – then it should be addressed as such. Perhaps the excipients should be listed, as occurs in the United States [Napke and Stevens 1984]. This matter is being addressed by the Health Protection Branch of the Department of Health and Welfare. It is anticipated that all excipients will be listed in alphabetical order on the labels of prescription drugs.

Another concern is that patient/consumers should be advised by the pharmacist when brand switching occurs. A number of issues arise here. First, the pharmacist may not know the prior brand. Second, it seems unlikely that patient/consumers have the relevant knowledge to make use of this information. Williams and Cockerill, in their survey of Ontario physicians, conclude that "a significant proportion of the prescriptions written in the province are not accompanied by review or counselling" [1989, viii]. Third, is the pharmacist the best avenue for this kind of information? Instead, perhaps governments could assure both consumers and prescribers of the safeguards and record of interchangeability by means of pamphlets, such as "Questions and answers on interchangeable generic products," published in 1990 by the New Brunswick Department of Health and Community Services, and a U.S. Federal Drug Administration pamphlet that was aimed at dispelling myths about generic drugs.[22] But there are other areas where the patient/consumer could receive information that are as, if not more, important, such as drug interactions for those on multiple medications, and whether a new medication is a replacement for an existing drug or a net addition to the patients'

regimen. In other words, the issue of brand switching should be seen as part of the much wider issue of the general provision of information and counselling to the patient/consumer.

Are Physicians Concerned about Brand Switching?

Physicians can express concern over the interchangeability of certain drugs by writing no-substitution prescriptions. Two classes of drugs, cardiovascular and anticonvulsants, have been singled out by the Ontario Medical Association [1988, 19] as being of particular concern when brand switching occurs. If these two therapeutic groups had high no-substitution rates, this would suggest that physicians share these concerns.

There were eight interchangeable groups of anticonvulsants in March 1989. The no-substitution rate of five was 0 per cent, and the rates of the other three ranged between 3.2 and 4.9 per cent. In the case of cardiovascular drugs, there were close to 50 groups of interchangeable drugs, none of whose no-substitution rates exceeded 8.3 per cent. Sixty per cent of them had no-substitution rates of less than 4 per cent.[23] These low no-substitution rates suggest that physicians were not very concerned about the interchangeable drugs in these two therapeutic categories.[24]

Furthermore, it might be noted that virtually without exception, the no-substitution prescriptions are for the brand-name product, not the generic brand. For example, of the 14,390 ODB claims in March 1989 for methyldopa 250-mg tablets, 451 were no-substitution prescriptions. Yet these were all for the brand-name product, despite the fact that as early as 1978 three generic brands were listed in the formulary.[25]

Whither No-Substitution?

The issue of interchangeability is not going to go away. Too much is at stake for drug firms – both brand-name and generic – and the ODB. Interchangeability, combined with a best-available-price system, results in savings to the Ontario government. Based on the available evidence, these savings have been achieved with no loss in quality of the drugs taken by the patient/consumer. Interchangeability also results in loss of market share to brand-name firms and gains in market share for the generic firms.

As noted above, the cost of no-substitution prescriptions to the ODB in 1988/89 was about $15 million. If the lower-priced interchangeable brands were prescribed instead, then the savings could be as high as $7.5 million. The most obvious solution to the problem of no-substitution prescriptions is simply to abolish them, as several provinces have done. If they were abolished, the ODB would pay for up to the lowest-priced interchangeable drug, irrespective of the brand prescribed or dispensed, unless the physician could justify, on medical grounds, the dispensing of the brand name. If a patient/consumer, however, preferred the brand-name product, for whatever reason, it is difficult to see how the ODB could prevent it from being dispensed. However, the question then arises, should the patient/consumer pay for the entire prescription – drug cost and dispensing fee – or the difference between the lowest-priced brand and the brand selected by the patient, as is the case in other provinces?

There are good grounds for favouring the former option. If it is assumed that patient-consumers do not have the expertise to diagnose and treat themselves, then it seems somewhat illogical to assume that they have the ability to detect therapeutic differences between interchangeable brands of the same drug. If the patient/consumer prefers the brand name for nontherapeutic reasons, there is even less of an argument for the public purse subsidizing this preference.[26]

However the issue of interchangeability is resolved, the role of the physician must be taken into account. Simply abolishing no-substitution prescriptions, without considering the physician, may lead to considerable antagonism between the government and the health professions. Furthermore, since the ODB accounts for only approximately 50 per cent of the Ontario market, brand-name firms still have an incentive to encourage physicians to write no-substitution prescriptions for patient/consumers outside that market. To the extent that this influences physicians, it will only add to their frustration at the abolition of no-substitution prescriptions.

A number of steps could also be taken. An obvious first step would be to establish better communication between the prescriber and the DQTC concerning interchangeability decisions. That there is a need for this is revealed by the finding that less than one third of physicians in Ontario are satisfied with their knowledge of equivalencies of similar drugs, equivalencies of different brands of a drug, and nondrug alternatives [Williams and Cockerill 1989, v]. The provincial Ministry of Health, the federal Health Protection Branch, and the DQTC did nothing to dispel the concerns raised by either the Ontario Medical Association or the brand-name firms. The Department of Health and Welfare did commission reports on bioavailability of oral dosage formulations of drugs used for systematic effects [Expert Advisory Committee on Bioavailability 1990*a*, 1990*b*].

Drug advertising comes under the federal Food and Drug Act R.S., cF-21, which contains the following provision:

> 9(1) No person should label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quality, composition, merit or safety.

At the present time the advertising component of this act is delegated by the Department of Health and Welfare to the self-regulating Pharmaceutical Advertising Advisory Board, which preclears pharmaceutical advertising and promotional materials and addresses complaints once an advertisement or other promotional material is in the public domain [Pharmaceutical Advertising Advisory Board 1988; Raison 1989].

The board is currently developing a Code of Advertising Acceptance that includes a measure to regulate advertising in which two or more brands of the same drug are compared. More stringent guidelines concerning, for example, the availability of scientific evidence upon which claims are made are likely to be established. Penalties will probably include withdrawal of an offending advertisement and/or the requirement that the advertiser print a correction. Quicker resolution of complaints concerning advertising is also likely to be part of the package expected to be completed in late 1991 or early 1992.

New Directions

In this section two types of strategies to promote cost-effective prescribing strategies are discussed.[27] The first strategy involves incorporating cost-benefit analysis as part of the criteria to be employed in deciding whether or not a single-source drug product should be eligible for reimbursement under the ODB. The second is improving the prescribing habits of physicians through various types of educational tools and patient-specific interventions.

Criteria for Eligibility of Single-Source Drug Products

Typically, before deciding whether or not to buy a product or a service, consumers carefully evaluate its worth, compare it with existing products on the market, and consider whether it fits in their budget. Such decisions are likely to be especially well researched where a large expenditure is involved. In other words, consumers weigh the costs and benefits. The frequency of purchase will likely vary considerably among goods to be purchased, with some enjoying considerable popularity, others not.

Health care is, as noted above, different from other goods, in that decisions relating to its utilization are not made, to a very large extent, by the consumer. In the case of drugs paid for by the ODB, utilization is a two-step procedure. First, the Ministry of Health, on the advice of the DQTC, considers if the product is to be an eligible benefit; and, second, the physician decides whether or not to prescribe the drug.

Cost-benefit analysis is currently not used in any systematic way by the ODB in the process of considering the listing of new products. This technique involves a careful comparison of the costs and benefits of a drug product and is analogous to the process that the consumer goes through prior to purchasing a good or service.[28] In other words, it attempts to mimic a well-functioning market.

The application of cost-benefit analysis to the assessment of whether a new drug product should be listed requires much preparation and thought before it is introduced. Decisions have to be made with respect to which costs and benefits are to be considered. These may include not only those that directly affect the patient/consumer's welfare, but also its impact on the health-care sector and society as a whole. For example, if the main impact of drug A is to reduce the incidence of hospitalization in a particular area, then these savings should be taken into account by the DQTC. Some portion of the savings on hospital facilities might be transferred to the ODB budget.

There are several difficult issues that arise in putting values to some important benefits and costs, issues that raise not only economic questions, but ethical ones as well. For example:

- How is the value of a life saved to be assessed?
- How is an increase in a person's mobility to be valued?
- How should benefits and costs that accrue at various points in time be discounted to the present, so that different time profiles of benefits and costs can be compared?

Another set of issues concerns the comparisons that are made when consumers make purchasing decisions. For example, they will typically compare good X with goods A to W that are close substitutes. Where the new higher-priced product X offers substantial advantages to a small group of consumers of goods A to W, then only this small group is likely to pay the higher price. If good X is

completely new, there may be no close substitutes for it, and a large number of consumers may purchase the good, even at a high price.

There are clear parallels in the drug area. The first drug of a particular type, A, is likely to be a breakthrough or major improvement over previous products. As such it may be compared with alternative surgical procedures and/or distant substitute drugs in considering whether it should be an eligible benefit. If the comparison is favourable, then A is likely to be listed in the formulary. However, the second and subsequent close substitutes should perhaps be compared with A. These substitutes are likely to be line extensions, or drugs that offer no, little, or moderate improvement. If these drugs offer additional benefits to only a subset of current patient/consumers of A, but at a substantially higher price, then access to these close substitutes may be restricted by, for example, placing them on the nonformulary benefit list. If they offer extra benefit to all patient/consumers but cost substantially more than existing drugs, then perhaps they should not be eligible for reimbursement or only be eligible at a price that reflects the additional benefits. Alternatively, the ODB could limit reimbursement to one of the close substitutes in return for price discounts, a practice adopted in some U.S. hospitals [Rosenthal 1991].

The available evidence suggests that most new drug products are line extensions, or drugs that offer no, little, or moderate improvement, rather than being breakthroughs or substantial improvements over previous products. In the period 1988-90, for example, new drugs introduced in Canada for human use were distributed across these three categories as follows: 46.9 per cent, 48.1 per cent, and 4.9 per cent, respectively [Patented Medicine Prices Review Board 1991, Table 2, 13].[29]

There is an extensive literature on cost-benefit analysis, and considerable thought has already been given to how it could be applied to drugs. One of the most extensive investigations was by the United States Office of Technology Assessment [1980*a*, 1980*b*]. It recommended that "the possibility of not aggregating the often complex sets of calculations should be . . . considered" [1980*a*, 29]. It suggested that all the elements to be included in the analysis should be listed or arranged so that they would be considered explicitly. The advantage of this approach, it claimed, was that it

> would give decisionmakers a greater number of elements to consider . . . [and] would also make intangible or nonquantifiable factors more explicit, and thus might help force consideration of these factors by decisionmakers commensurate with the factor's significance [1980*a*, 30].

Considerations of costs and benefits are becoming increasingly important in Ontario, as the discussion of special authorizations and nonformulary benefits earlier in this chapter demonstrated. The Pharmaceutical Inquiry of Ontario [1990*a*, 43] is in favour of a more effective evaluation of drug product cost factors, and the government of Ontario, in a supplementary paper to the 1991 Ontario budget on "Managing health care funding," lists five management initiatives for the ODB, one of which is very similar to the Pharmaceutical Inquiry's [Ontario Ministry of Treasury and Economics 1991, 13].

Other provinces have also made decisions that reflect cost-benefit considerations. One example is the treatment of H_2 receptor antagonists, which are used for the treatment of ulcers. The first drug in this class was cimetidine, followed by several close substitutes – ranitidine, famotidine, and nizatidine. On famotidine, the respected *Medical Letter* concluded that it "appears to be comparable to cimetidine or ranitidine in healing duodenal ulcers and preventing their recurrence. Famotidine may not interact with other drugs as often as cimetidine, but the full range and extent of its adverse effects remain to be determined" [13 February 1987, 18]. A somewhat similar statement appeared in the *Medical Letter* [12 August 1988] regarding nizatidine.

In terms of sales, ranitidine and famotidine were among the leading sellers in Ontario in 1989 (Table 7-2). Furthermore, while there is generic competition for ranitidine and cimetidine, there is none for the other two H_2 receptor antagonists. The market share in Ontario of the much cheaper cimetidine has been eroding continually at the expense of much more expensive, newer drugs (Table 7-5).

In Saskatchewan, ranitidine was not included in the formulary until July 1987, when two interchangeable brands were listed simultaneously. In Ontario, it entered the formulary in January 1983 as a single-source product. Quebec placed ranitidine (1983), nizatidine (1988), and famotidine (1987) on its exceptional drug list, because their higher cost relative to cimetidine did not outweigh the extra benefits they offered [Quebec Conseil Consultatif de Pharmacologie 1989]. However, because of "political influences" famotidine was transferred to the formulary in July 1989 [Pharmaceutical Inquiry of Ontario 1990*a*, 60]. It was listed in the Saskatchewan and Ontario formularies in July 1987.

Clearly, governments do have choices in deciding whether or not to pay for particular drugs. Some have exercised this choice for high-dollar-volume sellers, where the stakes are high both for the drug firm and the province. What is needed are systematic public criteria upon which such decisions can be based. This would not only ensure

Table 7-5

Distribution of claims for, and cost of, H_2 receptor antagonists, Ontario Drug Benefit, March 1986 and 1989

	As a proportion of ODB					
	Claims[1]		Costs[2]		Average cost per claim[3]	
	1986	1989	1986	1989	1986	1989
	(Per cent)				(Dollars)	
H_2 receptor antagonists						
cimetidine	52.10	24.72	22.60	9.75	13.41	17.36
ranitidine	47.90	66.68	77.40	79.08	49.91	52.18
famotidine	...	7.82	...	10.29	...	57.89
nizatidine	...	0.79	...	0.88	...	49.44
Total	100.00	100.00	100.00	100.00	30.91	44.00

1 The number of all claims for all dosage forms and strengths.
2 The cost, including dispensing fee, for all claims for all dosage forms and strengths.
3 Including dispensing fee.
Source: Ontario Drug Benefit, "Formulary utilization," computer printout, March 1986-89.

that the drug submission process is fair, but it would eventually bias R&D towards drugs that meet these criteria.

The responsibility to "establish, maintain, and apply criteria to evaluate the quality and therapeutic value and cost of drugs" and "to provide advice on relevant drug, pharmaceutical and therapeutic questions solicited or requested by the Ministry of Health from time to time" is part of the DQTC's terms of reference (see box on page 114). The design and implementation of cost-benefit procedures for single-source drugs would seem to come under these clauses. The DQTC could, after holding public hearings, recommend cost-benefit guidelines to be used in assessing drugs for inclusion in the formulary. It would, of course, have to keep physicians informed of its decisions, either through a newsletter or one of the techniques discussed in the next section.

Improving Physician Prescribing

Physicians should be able to prescribe in a cost-effective manner, providing that they have the relevant information and the correct incentives. The earlier part of this chapter suggested that there were good reasons, given the way in which the prescribing decision is made, why prescribing is not always optimally cost-effective. There are a number of ways that the provision of information to physicians and the incentives under which they operate can be improved. Here we draw upon the excellent surveys of Soumerai et al. [1989] and Carruthers et al. [1987].

Educating Physicians

The first group of techniques is aimed at educating the physician. If shortcomings in prescribing are caused by lack of information on the part of doctors – whether because of the difficulty in keeping up with the high volume of medical literature, the high turnover of new drugs, or excessive reliance on brand-name firms for prescribing information – what is the best way to provide this information? Analysts have studied various educational techniques, which are evaluated below.

Printed Matter — The Pharmaceutical Inquiry of Ontario [1990*a*, 108] recommended the creation and distribution of guidelines for prescribing and information on relative costs of drugs to all physicians in Ontario. The evidence suggests, however, that mailing such things as protocols, guidelines, and self-instruction manuals to physicians has very limited, if any, success [Soumerai et al. 1989, 273-79; Carruthers et al. 1987, 253].

Group Education — Oral interaction that relies "primarily upon traditional didactic learning to effect a change in physician behaviour" [Soumerai et al. 1989, 280] includes rounds, conferences, lectures, seminars, and tutorials. In a survey Ontario physicians reported that, between 1987 to 1989, they had attended, on average, "three seminars sponsored by physicians' groups and two continuing medical education courses" [Williams and Cockerill 1989, 28]. There is, however, very little evidence on the effectiveness of such seminars and continuing education courses despite

their widespread use. Apparently they "may change physician attitudes and knowledge; however, whether these effects result in improved prescribing practice remains unclear" [Soumerai et al. 1989, 282].

One-on-One — This involves medical experts visiting physicians in their offices to give them information concerning problem drugs or prescribing practice in a direct one-on-one situation. It may also be supplemented by printed material. The efficiency of this technique is suggested by its extensive use by brand-name drug firms to promote their products. The results of several carefully controlled experiments led Soumerai et al. to conclude that this technique, provided the counsellors are well trained, is "associated with practically and clinically significant improvements in prescribing." Furthermore, although they might be expensive, these programs "have been shown to save more dollars than they cost, and to improve quality of care" [1989, 291-92].

The Pharmaceutical Inquiry of Ontario [1990*a*, 111] recommended a pilot project of one-on-one education based on the studies conducted by Avorn and Soumerai. Of the three educational techniques considered here, it seems clear that only one-on-one educational programs have a proven track record that would recommend their use.[30]

Monitoring Physicians' Prescription Behaviour

The next group of techniques relies on monitoring patients and informing physicians about patient-specific drug usage and perhaps suggesting appropriate remedial action.

Drug Utilization Reviews (DURs) — Physicians' past prescribing patterns are examined, perhaps by a regulatory body, and, where significant discrepancies are found compared with some accepted standard, the physician is informed and the appropriate remedial action is suggested. Follow-up is conducted to evaluate the success of the intervention. Drug utilization or usage reviews are defined as "a formal program for assessing data on drug use against explicit, prospective standards and, as necessary, introducing remedial strategies to achieve some desired end" [Rucker 1983, 25]. There is a considerable literature on the way in which DURs should be structured,[31] their effectiveness,[32] while there are two working models in Canada, British Columbia,[33] and Saskatchewan.[34] Two recent reports to the Ontario government favoured the introduction of DURs.[35] Ontario is moving towards the establishment of a DUR system [Archer 1991, 115].

An alternative or supplement to retrospective DURs is providing the physician with feedback at the time of the prescribing action or shortly thereafter, possibly through the pharmacist. Information on the patient/consumers' drug use would be encoded on a "smart card," which would be read by computer programs that could detect problems. However, "virtually no data exist from well controlled studies demonstrating the efficacy of this approach" [Soumerai et al. 1989, 299]. Furthermore, it is not clear why the "smart card" could not be employed by the physician or his assistant before the prescription were written, which would detect problems earlier.

Patient-Specific Information: No Feedback — In this technique physicians are given patient-specific information on drug usage but no comment or advice. The four studies conducted in this area suggested that "merely reporting detailed drug use profiles of individual patients . . . is unlikely to affect the prescribing habits of busy physicians" [Soumerai et al. 1989, 281].

Reminders at the Time of Prescribing — Reminders would be automatically sent to the physician when any kind of follow-up on drug use is required. The evidence indicates that such reminders improve physician performance, but that once they are discontinued, they have no long-term effect. It appears that these reminders were more appropriate than teaching interventions [Soumerai et al. 1989, 284-87].

Two of the three patient-specific techniques appear to be effective in improving prescribing habits of physicians. When combined with the one-on-one educational technique, three have a proven track record for improving physician prescribing. They each have advantages and disadvantages, and some can be employed sooner than others. For example, before DURs can be used in Ontario, physician identifiers need to be recorded, so that patients, drugs, pharmacists, and physicians can be linked. Some of these techniques will be substitutes, others complements. Some will work better in some settings than others – for example, a group practice compared with a solo practice. Thus careful consideration will have to be given to their deployment and the results carefully monitored to ensure that the objectives are met and that the benefits exceed the costs.

Deployment — These educational and patient-specific techniques should only be employed where there are well-documented examples of inappropriate physician prescribing; there is a reasonable expectation that the benefits will outweigh the costs; and information is collected so that a retrospective evaluation can be conducted which is then made public. There are a number of sources of information about inappropriate prescribing. There is, of course, the medical literature. There are also other ways that the ODB could uncover it. Each time a new drug is added to the

formulary, its market size and impact could be estimated. Instances of substantial deviation could then be investigated to see if a problem exists. The ODB has drug profiles for its beneficiaries. These could be routinely monitored to detect problems. For example, for frequently prescribed drugs the following questions could be asked:

- Are they being prescribed in the correct quantities?
- Are they being prescribed for the correct duration?
- Are they being taken with other drugs where this is inappropriate?

The profiles of consumers who are heavy users of drugs should be examined, since the evidence indicates that adverse reactions are directly proportional to the number of drugs taken [Aoki et al. 1983]. New Brunswick recently moved in this direction by conducting a review of the use of benzodiazepine among drug plan beneficiaries (essentially the same population group as in Ontario). Based on three criteria of inappropriate use, during the first six months of 1990, 72 per cent of those aged 65 and over and 63 per cent of those aged under 65 used this group of drugs inappropriately [New Brunswick Department of Health and Community Services 1991].

New Directions: Full of Sound and Fury Signifying Nothing?

The two inquiries on drug usage commissioned by the Ontario government in the mid-1980s endorsed many of these ideas, and the College of Physicians and Surgeons of Ontario has become much more interested in monitoring and improving the quality of care provided by physicians.[36] These concerns are reinforced by the fact that Ontario has the second highest per-capita expenditure on drugs in the country (only Nova Scotia's is higher); for those aged 65 and over at least, this seems to be due to consumption of a large number of drugs. The former chairman of the DQTC resigned in 1987 because of the lack of progress on this and related issues. A critical mass in favour of these changes seems, however, to have been reached.

8 Conclusions

Many of the issues addressed in this study are of long-standing concern. Several cost-reducing measures have been introduced by provincial governments. Nevertheless, progress is frequently slow in implementing what appear to be at first sight, and indeed even after some reflection, sensible measures. Why? The answer lies partly with the policy-making process, and partly with an inadequate understanding of the outcome of various policy proposals.

The policy-making process is best seen as a continuing struggle between various groups, each with a direct economic and professional interest in the outcome. These groups include drug manufacturers – both brand-name and generic – prescribers, pharmacists, private third-party drug programs, and, to a lesser extent, patient/consumers. Each demands that the government supply certain policy "products" that will be most favourable to it, and that sometimes involves increasing costs.

Each of these conflicting demands carries a different price tag. The best-available-price model, preferred by generic drug manufacturers, is likely to result in lower drug costs than with the actual-acquisition-cost system, favoured by the brand-name drug manufacturers. The cost-based method of determining dispensing fees, preferred by pharmacists, would probably result in a higher fee than a market-determined fee combined with a copayment that is a percentage of the fee, the system advocated by many analysts (including the present author).

Nevertheless, despite this knowledge, the most cost-effective programs are not always implemented, perhaps out of a concern not to trespass on the professional integrity of a particular group. Over time, however, as drug costs have risen substantially, and as provincial governments have become responsible for paying a higher proportion of them, they have become more willing to infringe on the professional and economic objectives of the various groups involved – as they must do if controlling costs is to be anything more than idle rhetoric.

An alternative approach is for the government to withdraw from attempting to control drug costs, by leaving the provision of drug plans totally to the private sector, and only subsidizing people on welfare and those who have very large drug bills. In other words, cost control is exchanged for cost transfer. This would not, however, solve the problem of steadily rising expenditure on drugs; indeed, it could lead to higher costs.

Governments have intervened extensively in a variety of ways to control drug plan costs. One way has been to promote price competition by introducing interchangeability together with price and product selection rules, or charging patient/consumer copayments as a percentage of the pharmacists' competitively set dispensing fee. Another has been to use the government's large buying and bargaining power to secure lower prices when negotiating dispensing fees or purchasing drugs on a tender basis. That these measures are necessary is a reflection of the oligopolistic nature of the drug industry and the explicit restraints on price competition in the pharmacy market.

There is also a role for the government to act as an agent for patient/consumers and other payers in their relations with the sellers of drugs and pharmacy services. Consumers are usually not qualified to make judgments on the therapeutic advantages and disadvantages of particular drugs or the substitutability of two brands of the same drug. Even where consumers have the ability to judge some services, for example, some pharmacy services, there needs to be an incentive for them to select the pharmacy with the lower fee.

But the government cannot just set the rules of the marketplace and then stand back. Competition is antithetical to the interests of many of the groups affected by government intervention. Once a system promoting competition is introduced, those groups that are adversely affected will respond by attempting to reduce, if not eliminate, the impact of the policy. The discussion in Chapter 6 demonstrated this with respect to interchangeability. Thus the government needs to continuously monitor the marketplace and have the flexibility to respond.

Of necessity, the government has to play an ongoing role in the marketplace, whether it be funding and running a drug plan or only setting the rules of the marketplace. Nevertheless, when the government is unable to externalize the cost of its decisions – in other words, when it has to pay for the effects of its own cost-increasing policies – then it is much more likely to take the hard political decisions required to control costs as opposed to transferring them.

A Terms of Reference and Recommendations of the Review Committee on Prescription Product Substitution (Porter Committee) and the Ontario Drug Benefit Formulary Pricing Committee (Bailey Committee)

The terms of reference and recommendations of the Porter and Bailey committees are reproduced here because they are not widely available.

Porter Committee

Terms of Reference

On 26 February 1971, the committee was directed by the then Minister of Health to:

> consider the question of permitting pharmacists when dispensing a prescription to select, from the PARCOST comparative drug index, an alternate product containing identical amounts of the identical active ingredient in an identical dosage form.

The committee's specific terms of reference were:

- To study and analyse the various proposals made by the professional bodies;

- To examine possible methods of implementing those proposals and the desirability of legislation;

- To examine the legal implications of the proposals;

- To examine the various forms of public safeguards, for example, labelling prescriptions with the name of the drug, dose, manufacturer's name, and so on;

- To examine the relationship of the proposals to the PARCOST program; and

- To report to the Minister of Health on the effectiveness of the various procedures that may be adopted.

Recommendations

1 Unless directed otherwise by the prescriber, a pharmacist when dispensing a prescription for a product listed in the *PARCOST Comparative Drug Index* may select and dispense a comparable pharmaceutical product* provided that the cost of such product to the consumer is equal to, or lower than, the lowest-priced comparable pharmaceutical product listed in the *PARCOST Comparative Drug Index*.

2 We further recommend that the pharmacist be required to label all prescriptions with the name of the drug product as well as the strength and the manufacturer's identity.

* Those products listed in the *PARCOST Comparative Drug Index* which contain identical amounts of the identical active ingredients in identical dosage forms.

Bailey Committee

Terms of Reference

In October 1977, the committee was directed by the Minister of Health "to advise on the possibility of improving the present system of establishing the prices listed in the Ontario *Drug Benefit Formulary*" (Bailey et al. 1978, 1).

The terms of reference of the committee were:

- To review the current policies and procedures used in establishing the package sizes and prices listed in the Ontario *Drug Benefit Formulary*/*PARCOST Comparative Drug Index*;

- To determine whether or not the existing system is appropriate in view of today's marketing practices, and to identify any problems that may exist;

- To consider alternatives; and

- To make recommendations for improvements.

Recommendations

To improve the effectiveness of the Ontario Drug Benefit program it is recommended:

1 That the Ontario *Drug Benefit Formulary* should disclose only the lowest price quoted on interchangeable products. All other products in each interchangeable group should be listed in alphabetical order. The government should not produce a price book that can adversely influence drug costs for the remaining 75 per cent of the prescription market.

2 That the prices of the other products in an interchangeable classification shall be considered to be the actual acquisition cost to the pharmacy.

3 That consideration should be given to using the phrase "invoice cost" rather than "actual acquisition cost" if this is more practical.

4 That Section 158 of the Health Disciplines Act should be revised if necessary to accommodate this change in the *Drug Benefit Formulary/*PARCOST *Comparative Drug Index.*

5 That for those products whose volume is such that the average pharmacy purchases 1,000 units per month, quotations in the Ontario *Drug Benefit Formulary* should be based on the cost per 1,000.

6 That this volume could be established through a review of the claims submitted to the Ontario Drug Benefit. Where the total volume exceeds 450,000 units per month for a given product, it can be assumed that the average pharmacy is capable of purchasing 1,000 units of such products monthly, since Ontario Drug Benefit claims only account for 25 per cent of Ontario prescription expenditures.

7 That the effect of the above changes should be assessed after a six-month period and adjustments made accordingly. If it is impractical for the average pharmacy to purchase these high-volume products in 1,000's, adjustment could be made to either 500's or other smaller packages. Similarly, if additional products reach this utilization level, they should be added to the list of large package-sizes.

8 That the Ontario *Drug Benefit Formulary* should specify the package size used in determining the product prices listed.

Additional Proposals

Although the following considerations may be beyond our terms of reference, we feel obliged to make these comments because the delegates from both the Ontario Pharmacists' Association and the Drug Trading Company, in their presentations, insisted that any change in package sizes listed in the formulary must not be implemented until consideration is given to other aspects of the program such as the Ontario Drug Benefit dispensing fee and the overall remuneration of the pharmacist.

We recognize that this is a valid point and we have therefore given due consideration to the various components of the pharmacists' reimbursement and alternative approaches to the provision of an efficient program which will not adversely affect the prescription drug market in general.

With the above factors in mind, we recommend:

1 That future negotiations with the pharmacists should acknowledge that a reasonable extra margin should be allowed to the retail merchant who buys in quantity and at less frequent intervals, since the normal economies of scale should prevail. We feel, however, that such extra profit should not exceed the normal 10 to 20 per cent which might be expected on quantity purchases of any other type of commodity.

2 That manufacturers should be cautioned about quoting fictitious prices for formulary listings of their products. To put teeth into this warning, the ministry should question the corporate responsibility of any manufacturer that fails to meet this criterion and, if necessary, delist products of any manufacturer engaged in this practice.

3 That provision should be made to enable the cash-paying public to make a rational choice of pharmacies when having prescriptions filled. Pharmacies should be allowed to declare their dispensing fee through both the advertising media and by means of discreet plaques or cards at the pharmacy entrance or in the dispensing area.

4 That the government should encourage fair pricing policies by enabling the public to have a standard by which to compare the providers of prescriptions. This could be done by periodically making the public aware of the price paid by the government for Ontario Drug Benefit prescriptions. This could be done through the news media and the public should be made aware of three factors:

- The current fee paid by government for prescriptions under the Ontario Drug Benefit;

- The fact that in Ontario less costly products are frequently available among the high-dollar-volume drugs; and

- The fact that these interchangeable products are comparable in quality to the more expensive products frequently prescribed.

5 That the plastic eligibility cards currently issued to all Ontario citizens aged 65 and over should be used more effectively as they would be in any other business. To minimize the danger that the taxpayer may be paying for prescriptions which were never filled, the identification cards should be presented and used in the appropriate machine in every pharmacy each time a prescription is filled. The

recipient of the prescription should sign a receipt which could be forwarded to the ministry along with drug benefit claims for reimbursement. We believe that the public would thus share the responsibility for these claims and that a more accurate audit trail could be established through this mechanism.

6 That the common practice of dispensing only 30 days' medication to senior citizens should be modified in view of the fact that most of these individuals are on long-term therapy and many find it inconvenient to visit the pharmacy monthly. Dispensing of more rational quantities at one time should result in substantial economies to the pharmacy. These savings could be passed on to the taxpayer, and at the same time the hardship of repeated visits to the pharmacy by the Ontario Drug Benefit recipients could be alleviated.

7 That a token portion (copayment) of the prescription be paid by the Ontario Drug Benefit recipient to discourage overutilization of drugs and to account for part of the dispensing fee. Even a 50¢ copayment would result in a sizeable saving to the taxpayer.

8 That consideration should be given to a revision of the legislation requiring the use of child-proof containers on every prescription in Ontario. Prescriptions for individuals aged 65 and over should have more convenient closures unless otherwise specified. This would make it easier for senior citizens to obtain their medication and it would reduce the cost of prescriptions in this province. In the opinion of the committee, the risk of child poisoning in the homes of the elderly is outweighed by the danger of making vital medication inaccessible to those most in need.

Notes

Chapter 1

1 This discussion follows Schieber [1987]. See also R. G. Evans [1985*a*, 1985*b*]; and Grenier [1985].

2 On the importance of access as an objective, see Grenier [1985], Manga [1987], and various annual reports under the Canada Health Act, 1984; on the development of government intervention, see Taylor [1987]; on resource-allocation problems, see Lalonde [1974, 26-30]; and generally, see R. G. Evans [1983*a*, 1983*b*, 1985*a*, 1985*b*].

3 For example, Alberta Premier's Commission on Future Health Care for Albertans [1989]; New Brunswick Commission on Selected Health Care Programs [1989]; Nova Scotia Royal Commission on Health Care [1989]; Ontario Premier's Council on Health Strategy [1989] and associated background studies; Quebec Commission d'enquête sur les services de santé et les services sociaux [1988]; Saskatchewan Review Committee to the Minister of Health [1989]; Hall [1980]; and British Columbia Royal Commission on Health Care and Costs [1991].

4 These are the cornerstones of Canada's publicly funded health system. See Canada Royal Commission on Health Services [1964, 1965]; and annual reports under the Canada Health Act.

5 On the ramifications of the "greying" of society, see Fellegi [1988]; Economic Council of Canada [1989, 54-61]; "How best to help the aged," *Manchester Guardian Weekly*, 8 April 1990; and Callahan [1987].

6 Fellegi [1988, 41]. See also Canada Department of Health and Welfare [1989*a*] on Canada's changing population.

7 For further information, see Anderson [1989, 1990]; Canadian Pharmaceutical Association [1989]; Gorecki [1981, 1986*a*, 1986*c*]; Hurley [1989]; and Commission of Inquiry on the Pharmaceutical Industry [1985].

8 By 1991, however, Nova Scotia had a copayment mechanism.

Chapter 2

1 There seems to be a consensus that recent mergers in the drug industry are part of an industry-wide trend [Blackhurst 1989; Buchan 1989; *The Economist* 1989, 1990]. Blackhurst discusses the merger of Smith Kline Beckman of the United States and Beecham of the United Kingdom, one of the biggest so far.

2 Other explanations include a shift in demand to those therapeutic classes where drugs are more expensive. This does not seem to be a tenable explanation, since in Saskatchewan in the period 1984-87 there did not seem to be large shifts in prescription volume between pharmacologic-therapeutic categories [Saskatchewan Health Prescription Drug Plan 1987, 15-16].

3 All the drugs cited are listed as benefits under the ODB except AZT [Ontario Ministry of Health 1989*c*]. However, AZT is provided by the provincial government through another program.

4 Based on data in Table 7-1. The fiscal years are approximated by taking the averages of the last and first six months. In other words, the fiscal year ending 31 March 1988 is approximated by the period July 1987 to June 1988.

5 The ODB administers the drug plan for those on general welfare and family benefits on behalf of the Ontario Ministry of Community and Social Services, which supplies estimates of the eligible population. In recent years these have turned out to be quite conservative – below the actual number of beneficiaries. As a result, the estimate was increased to match the number of beneficiaries.

6 For those in institutional care and home care.

7 Based on Ontario Ministry of Health, "Drug benefit utilization report by plan type, 1987-88 fiscal year, summary report," 11 July 1988, mimeo.

8 The drug cost per prescription in Saskatchewan for 1986/87 does not appear to increase with age; however:

	Drug cost per prescription	Average drug plan payment per beneficiary
	(Dollars)	
Age		
65-74	12.58	233.02
75-84	11.31	260.30
85 and over	8.94	245.63
All beneficiaries	11.73	105.65

Source: Saskatchewan Health Prescription Drug Plan [1987, Table III, 19].

The drug plan payment does not include the up to $3.95 patient/consumer copayment per prescription. The decline in

drug cost per prescription with age may be the result of the hospitalization or death of those taking the more expensive medication.

9 Before 1983/84, the *Annual Report* of the Saskatchewan Health Prescription Drug Plan treated all those aged 65 and over as a single group. In 1987/88, the drug plan underwent considerable changes that may have affected utilization patterns. During the period 1983/84 to 1986/87, Saskatchewan had a maximum patient/consumer copayment of $3.75 per prescription from 1 January 1983 to 1 January 1984, when it increased to $3.95. The actual average patient copayment was $3.71 on 31 March 1983 and $3.79 on 31 March 1987. Thus the nominal charge remained unaltered. To the extent that inflation eroded the real price, some of the increase in Figures 2-1 and 2-2 may be due to a demand response.

10 If instead the indicator used is the average number of prescriptions per eligible beneficiary, then this increased across all age groups. Those in the two youngest groups and those over 85 had the largest increase, followed by those in the 75-84 age group, and then those aged between 45 and 74.

11 The values of $\propto$, Z, and $\bar{q}$ are taken from Table 2-2, while $4c$, df, and the consumer price index are from the same source as Table 2-1. Thus for 1981/82, $TE = 0.89 \cdot 1{,}277{,}640 \cdot 18.8$ ($5.41 + $3.89); for 1987/88, $TE = 0.96 \cdot 1{,}584{,}233 \cdot 22.5$ ($7.47 + $4.35). Note that there are minor differences in the sample of ODB drugs used in Tables 2-1 and 2-2. However, it is unlikely that this will substantially change the conclusions drawn below from Figure 2-5.

12 Data is not readily available for the ODB on the values of $\propto$ and $\bar{q}$ for those aged 65 and over. However, they are available for Saskatchewan for those aged 65-74, 75-84, and 85 and over. The first year that these were published was 1983/84. The assumption was made that the ratio of, say, $\bar{q}$ for each of the three age groups to $\bar{q}$ for all those aged 65 and over was the same in Ontario and Saskatchewan. The age structure in Ontario of those aged 65 and over was available for 1981, with a prediction for 1991 (information supplied by the Pharmaceutical Inquiry of Ontario, based on Statistics Canada data). Using the estimated values of $\propto$ and $\bar{q}$ for the three age groups 65 and over for 1981/82, together with the change in the age structure, the predicted increase in $\propto$ by 1987/88 was 0.01 to 0.90 and the predicted increase in $\bar{q}$ was 0.1 to 18.9. Several assumptions should be noted: the 1987/88 age structure for Ontario is proxied by that forecast for 1991; all ODB recipients are aged 65 and over; and Saskatchewan is a good proxy for Ontario with respect to $\propto$ and $\bar{q}$ by age group. Unfortunately, we have no way of verifying the validity of these assumptions.

13 $TE = 0.96 \cdot 1{,}277{,}640 \cdot 22.5$ ($5.41 + $3.89).

14 $TE = 0.90 \cdot 1{,}277{,}640 \cdot 18.9$ ($5.41 + $3.89).

15 The age structure of Ontario in 1981 and 1991 was as follows:

	1981	1991
Age		
65-74	61.79	59.68
75-84	29.83	31.49
85 and over	8.37	8.83

16 At least, because there are costs involved in raising $1 in taxes. See Tarasofsky [1984] for a discussion of the estimates.

17 This section is based on Barer et al. [1979]; and Evans and Williamson [1978].

18 In this context, private means not only those persons not covered by the ODB but also any payment ODB recipients may be asked to make.

Chapter 3

1 Gorecki [1981] discusses the introduction, rationale, and use of the 1969 legislation and the Drug Quality Assurance Program. The division of responsibilities between the federal and provincial governments reflects their differing jurisdictions.

2 On Parcost, see Ferguson et al. [1973]; Dyer [1974]; Gorecki and Klymchuk [1980]; and Segal [1973]. Dyer, for example, says:

> When this program was proposed in 1968, preliminary investigations indicated that practitioners were influenced by the illusion that inexpensive drugs meant inferior quality. It became apparent that an Index listing the cost of drugs of assured quality was required by practitioners to select more economical drugs [1974, 2].

3 Defined as "those products listed in the *Parcost Comparative Drug Index* which contain identical amounts of the identical active ingredients in identical dosage forms" [Porter et al. 1971, 1].

4 Dyer [1974]; Gordon [1984, 26]; and Gorecki [1982, 358-59]. The actual legislation reads as follows:

> 52–(1) Every person who dispenses a prescription may, unless otherwise directed by the prescriber, select and dispense an interchangeable pharmaceutical product other than the one prescribed, provided that the interchangeable pharmaceutical product dispensed is listed as interchangeable in the Parcost C.D.I. and is lower in cost than the drug prescribed.
>
> 52–(2) No person shall knowingly supply an interchangeable product under subsection 1 at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product in his inventory and the maximum dispensing fee as set out in the Parcost C.D.I.
>
> 52–(3) No action or other proceeding lies or shall be instituted against a prescriber or pharmaceutical chemist on the grounds that an interchangeable pharmaceutical product other than the one prescribed was dispensed in accordance with this section.

5 See also Dyer [1974, 10-11]. These four brands appeared in the first *Drug Benefit Formulary*. See Ontario Ministry of Health [1974, 35].

6 The relevant section of the Health Disciplines Act was 155, which closely parallelled section 52 of the Pharmacy Act (see note 4).

7 See Economic Council of Canada [1979, 48-49]. The same rationale applies to the Drug Quality Assurance Program at the federal level.

8 In 1989 benefits were extended to cystic fibrosis and thalassaemia patients [Ontario Ministry of Health 1988*d*, 1-2]. People who were ineligible because their income was just above the cutoff point for social assistance would – with the creation in October 1989 of a "buffer zone" for health benefits – "still be able to receive these benefits" [Ontario Ministry of Community and Social Services 1989, Fact Sheet #1].

9 This applies to most ODB beneficiaries. However, for those in long-term care facilities, the ODB card is presented to the pharmacist on the beneficiaries' behalf.

10 If, however, the physician prescribes Valium (or any other brand name), specifies "no substitution" on the prescription, and completes a Special Drug Requisition form (a PC-34), the Valium would be dispensed and reimbursed at $0.0702 per tablet. In the early 1980s, no-substitution prescriptions accounted for less than half of 1 per cent of all ODB claims (for details see Table 6-1).

11 Under the agreement, upon receiving a prescription for more than a month's course of treatment, pharmacists could "provide to the eligible person one month's supply." The maximum that could be supplied at any one time was a six-month supply. Such larger quantities could be provided, for example, in the case of "the absence of the eligible person from Ontario for longer than a month." In such instances, the fee would be that "charged by the Pharmacy to a cash-paying patient for such increased supply."

12 This statement has appeared at the top of an ODB program summary for management since at least the early 1980s.

13 See Pharmaceutical Inquiry of Ontario [1988*b*, 12-14] under the heading "Special High Risk Groups"; and Ontario Ministry of Health [1988*d*].

14 For example, the Ontario Ministry of Health [1976, 30] described this new concept of reimbursement as being "based on a marketplace system of competition."

15 Ontario Ministry of Health [1978, 39-40, 1979*a*, 37]. The list is reproduced in Gordon [1984, Appendix A].

16 Diazepam 10-mg tablets were not on the list of 30 high-volume interchangeable drugs; the lowest price in the July 1983 formulary was $0.0225 and in February 1984, $0.0237.

17 Ministry of Health memoranda [see Gorecki 1981].

18 However, if the prescription is written generically, the pharmacist must charge no more than the cost of the lowest-priced interchangeable pharmaceutical product in his inventory.

19 A federal inquiry into the national drug industry devoted one chapter to the retail pharmacy market and recommended copayment, greater competition, and the provision of more information to the consumer [Commission of Inquiry on the Pharmaceutical Industry 1985, 395-412].

20 The council also prepared a paper entitled "Medications and the older adult" that had a list of questions senior citizens should ask health professionals about drugs. These questions were distributed to senior citizens by the ODB [Ontario Advisory Council on Senior Citizens 1985, 4-5].

21 For details see *R. vs. Metropolitan Toronto Pharmacists' Association*, 1984, 3, *Canadian Patent Report* (3d) 233 (Ont. M.C.J.).

22 These conclusions are based on an examination of the Minutes of the Standing Committee on Social Development, which considerably amended Bills 54 and 55; conversations with representatives of the Ministry of Health and pharmacies; and letters written by pharmacists as part of a letter-writing campaign [in Ministry of Health files]. The Ontario Pharmacists' Association also took out newspaper advertisements in reaction to Bills 54 and 55, with the heading "Prescription for trouble!" [e.g., see *The Globe and Mail*, Toronto, 22 November 1985, A21].

23 With the notable exception of those "eligible for general assistance under the General Welfare Assistance Act" (Section 8 (1)(a) of Ontario Regulation 689/86 under the Ontario Drug Benefit Act). For this group, the maximum quantity dispensed per fee cannot exceed a 35-day course of treatment (see Table 2-2 for an indication of the size of this group).

24 There was considerable debate over the meaning of "best available price." During the hearings into Bills 54 and 55, a senior official of the Ministry of Health, Dr. Psutka, remarked: "In dealing with this matter for over a year and a half now, the concept of best available price has been debated at great length and there seems to be a lot of confusion even now" [Ontario Standing Committee on Social Development, 29 April 1986, S-36].

25 While Bills 54 and 55 were going through the legislature in early 1986, the authority of the Minister of Health to use price data other than that submitted by the manufacturers in setting formulary prices for drugs was challenged in court. This delayed the implementation of more realistic prices in the formulary. However, the minister's authority to use other such data was sustained. The act would appear to clarify that authority. (For details of the court cases see Ontario Standing Committee on Social Development, 16 April 1986, pp. S-6 to S-8.)

26 See Ontario Standing Committee on Social Development, 29 April 1986, pp. S-27 to S-31.

27 Extra because the legislation already provided for this possibility. However, the paperwork involved was felt to be "excessive."

28 Section 2 (1) of Ontario Regulation 691/86 under the Prescription Drug Cost Regulation Act. Prior to the passage of this legislation, there was no mandatory requirement for posting fees inside the pharmacy.

29 In a letter to all pharmacists in January 1987, the Ontario College of Pharmacists provided one instance in which a different fee could be charged. If the pharmacist's cost of the drug is above that listed in the formulary, then the difference can be added to the fee, with an explanation to the patient/consumer. This appears to apply to all drugs, single source as well as interchangeable.

30 The regulations passed pursuant to the Health Disciplines Act, however, specify that "submitting an account or charging a fee for any service as a pharmacist that is excessive or unreasonable in relation to the service provided" is professional misconduct.

31 Green Shield sets a maximum fee, a "weighted average fee set every six months based on posted fees as reported to us and the volume of prescriptions dispensed in the preceding period" [Green Shield Prepaid Services Inc. 1988, 9].

32 Section 7 (2)(d) of the Prescription Drug Cost Regulation Act. If the prescription contains the generic name of the drug, then the pharmacist must charge the lowest BAP for the interchangeable products in his inventory.

33 A similar rule applies within the ODB for "no substitution" prescriptions, except that the physician is required to complete a PC-34 form.

34 In 1986, approximately 60 per cent of drugs were purchased through wholesalers and 40 per cent through manufacturers or agents. If one applies these numbers to 1987, when total ODB expenditure on drugs was $346.2 million, 4 per cent is $13.8 million. There are about 2,000 pharmacies in Ontario.

35 In 1985, the size of the spread was estimated by the Ministry of Health to be $3 to $4 million a month for the whole Ontario market [Elston 1985, 2]. If the margin remained constant, it totalled between $36 and $48 million annually. The ministry has subsequently suggested that the loss of spread was closer to $30 million [Ontario Ministry of Health 1988*c*, 12]. While these numbers are not precise, they do suggest that the 10-per-cent margin was adequate to compensate the pharmacist for the loss of the spread.

36 This is not the view of the pharmacists. They see it as embodying the concept of purchasing advantage. However, as the discussion in the chapter makes clear, the 10-per-cent margin does not seem to be related to Bailey and Gordon's definition.

37 Quoted from a letter dated 18 January 1988 entitled "Re: Drug Quality and Therapeutics Committee," from S. G. Carruthers, Chairman, Drug Quality and Therapeutics Committee, to Elinor Caplan, Minister of Health. See also McLaren [1988].

Chapter 4

1 For details of the discounting, see *Annual Reports* of the Saskatchewan Health Prescription Drug Plan up to 1987. After 1987 the copayment system changed. The discounting had some impact, since attempts were made to discourage its use. See Anonymous [1986] for details.

2 However, the members of the inquiry did discuss copayment at length. Indeed, it spent more time on this issue than any other.

3 This does not, of course, apply quite as neatly to copayments linked to the total cost of the prescription. However, these are rare in Canada. They were introduced in Saskatchewan in part to reduce the incidence of no-substitution prescriptions, which are not anywhere near as important a problem in Ontario. This is discussed further in Chapter 5.

4 The Ontario Drug Benefit Act does allow, under Section 7 (3), the establishment of "classes of operators of pharmacies and provide for an amount payable in respect of each class." In a number of provinces the dispensing fee falls after a certain volume of prescriptions.

5 In the non-ODB market, the pharmacist must specify what services are provided for the posted fee: patient profiles, professional consultation, health-care information services, after-hours emergency prescription service, and delivery service. The pharmacist may charge extra for some of these.

6 See also Gorecki [1981, 5-7]; Ontario Pharmacists' Association [1988*b*, third position paper]; United States Department of Health and Human Services [1990*a*, 1990*b*]; and Cureton and Jay [1990].

7 Ontario Regulation 698/86, Section 8 (2), under the Ontario Drug Benefit Act, 1986. It should be noted that for certain classes of beneficiaries under the ODB, such as those who are eligible for general assistance under the General Welfare Assistance Act, the province only pays for a 35-day supply because beneficiaries qualify on a monthly basis.

8 The 1987 use of the FNC set the fee for the period from 1 December 1986 to 30 November 1987; the 1988 use of the FNC set the fee for the period from 1 December 1987 to 30 November 1989. For the period from 1 December 1989 to 30 November 1990, the fee was set without resort to the FNC.

9 This discussion follows closely Gordon [1987, 4-6].

10 In some instances, however, it reflects a readily available or convenient package size.

11 Some senior officials at the Ministry of Health took the view that the one month was a minimum, but apparently to no avail, since this was generally interpreted by pharmacists to be the maximum as well.

12 The Ontario Drug Benefit Act appears to have largely replaced the Participation Agreement.

13 To be included in the sample, a drug had to be designated "circle one" in the January 1985 formulary [Ontario Ministry of Health 1985*b*]; have cost the ODE over $100,000 (including dispensing fee) in March 1986; and the ODB must have paid for at least 450,000 units of the drug in March 1986. Thus the sample is important in terms of expenditure and has enough quantity to suggest the average number used will not reflect one or two outliers. March was selected because it was the most recent month for which data were available. Also, in the fall many ODB recipients go to the United States and buy large quantities of drugs, so there is a possibility of bias. There seems to be no particular bias in selecting March.

14 Many provincial governments, in their negotiations with physicians, have been able to reduce fee increases. To the extent they have been successful, physicians may offset the lower fee increases by increasing the number of billings [Barer et al. 1988, 3], perhaps through more frequent visits for prescription renewals [Pharmaceutical Inquiry of Ontario 1990*a*, 98].

15 The incidence was much lower in Quebec [Quebec, Régie de l'Assurance-maladie du Québec 1984, Tableau F, 192]. In 1990 roughly 70 per cent of prescriptions filled in Ontario were verbal, which, combined with the fact that ODB inspectors did not verify verbal prescriptions, led the provincial auditor to conclude that the ministry was vulnerable to false billings [Archer 1991, 113].

16 See the following articles in the bulletin for third-party prescription programs published by the B.C. Pharmacists Society, "Special notice re prescription quantities," *Mittee III* 7, no. 4 (May 1982); and "Pharmacare," *Mittee III* 11, no. 4 (February 1986).

17 British Columbia is one of the few jurisdictions in North America that conducts competency tests. Saskatchewan carries out drug utilization reviews. Ontario has made some moves towards introducing competency tests, following the recommendations of Schwartz [1989]. Bill 43, "An act respecting the regulation of health professions and other matters concerning health professions," which received first reading on 2 April 1991, under the Health Professions Procedural Code, permits a "program designed to evaluate the knowledge, skill and judgement of the member" (Section 80 (1)(e)). This was recommended as far back as 1970 by the Ontario Committee on the Healing Arts [1970, vol. 1, 28, recommendation 116]. On the United States, see United States Department of Health and Human Services [1990*b*, 12-13].

18 For four drugs, comparable data were not available for British Columbia, and triazolam 0.5-mg tablets were not listed in Ontario as an eligible benefit in 1989. For ease of computation, therefore, a sample of 35 drugs was used.

19 The Pharmaceutical Inquiry of Ontario [1990*a*, 194] misinterpret these results as meaning that the B.C. data indicated that all maintenance drugs were prescribed for courses of 250 days.

20 A simple example illustrates the point. If total claims = total quantity dispensed/average quantity dispensed per claim, then total claims = 300, total quantity dispensed = 9,000, and average quantity dispensed = 30. Now suppose we assume that total quantity dispensed remains unchanged, but average quantity dispensed increases by 50 per cent to 45, then total claims decline to 200, a drop of one third.

21 Thus for 30 per cent no effect would be felt, but for 70 per cent there would be a fall of one third to 46.67 per cent. The new total with a dispense-as-written policy would be 76.67 per cent. The 20 per cent in the text is thus an underestimate.

22 The Pharmaceutical Inquiry of Ontario [1990*a*, 99] suggests that the associations representing physicians and pharmacists as well as the professional regulatory bodies study this problem together. It is not clear why the economic interests of physicians and pharmacists should be included; if they are, then surely counteracting forces, such as the Ministry of Health, should also be included.

23 For ODB claims where the entire quantity is not dispensed and no professional reason is provided, an automatic fine can be imposed. The Ministry of Health already conducts routine audits of pharmacists.

24 The issue was examined in British Columbia and Nova Scotia. The B.C. experience is discussed extensively below. In Nova Scotia, the introduction of a copayment of $3 in June 1990 resulted in a 7.1-per-cent increase in the length of the course of treatment across all claims. This percentage was derived by a comparison of the average number of days' supply in the last three months of 1989 and 1990. In the latter period, the average number of days' supply was 33 days. For further details, see Maritime Medical Care Incorporated [1991, 8].

25 This concerned the Metropolitan Toronto Pharmacists' Association and Green Shield. The former was charged under the Combines Investigation Act but was acquitted [Director of Investigation and Research 1985, 46-47].

26 The ministry felt that existing differences between fees in the ODB market and those in the non-ODB market were not justified on a cost basis [Ontario Ministry of Health 1988*b*, 20].

27 Fees in other jurisdictions do not seem to be substantially higher than those in Ontario [Ontario Ministry of Health 1988*b*, 48; Anderson 1989, 1990]. Furthermore, pharmacists have the option of not participating in the ODB.

28 The argument that in the mid-1970s pharmacists' usual and customary fees were set slightly above the ODB fee and then used as an argument for ODB fee increases seems much less tenable for the late 1980s, in view of the position taken by the chairman of the Fee Negotiating Committee that fees

should be decided on the basis of a survey of the costs of dispensing [Gordon 1987, 1988]. The Ontario Pharmacists' Association seems to have accepted this position [Gordon 1988, 3]. Furthermore, in its brief to the Pharmaceutical Inquiry of Ontario, the OPA [1988*b*, third position paper, 22] argues for ODB fee increases in terms of costs, not the disparity between the ODB and the usual and customary fee.

29 In Australia, a similar discussion occurred over the appropriate size of pharmacy on which to base the fee cost estimation. The government wanted a larger size, and the pharmacists wanted a smaller size [Australia Bureau of Industry Economics 1985, 33].

30 Costs might also be too low if the provincial government were to use its substantial bargaining power to prevent appropriate fee increases. However, it is difficult to square this with the increase in the number of pharmacies in Ontario.

31 If the 1986 legislation had introduced effective competition, one might expect the non-ODB fee to fall relative to the ODB fee. However, there was no such trend. If anything, the reverse was true. The ratio of the mean private or non-ODB fee to the public or ODB fee rose from 1.15 on 20 March 1987 to 1.35 on 31 December 1989.

32 Two of the referees of this study took somewhat different views. One argued that the saving in used drugs was double the cost of the additional fees; the other that there were substantial savings for a very small number of drugs. Perhaps the lesson to draw from these conflicting views is that prescription quantities should be carefully monitored and the results widely disseminated.

33 To use Hirschman's terminology, the government is exercising the option of (partial) exit over voice [1970].

34 *Rocket vs. Royal College of Dental Surgeons of Ontario*, Supreme Court of Canada, 1990, File 21019, unreported.

35 See Ross [1966]; Canada Royal Commission on Health Services [1965, 21-38]; Commission on Pharmaceutical Services [1971]; Ontario Committee on the Healing Arts [1970, vol. 2, 216-43]; Pharmaceutical Inquiry of Ontario [1989*b*, 1989*c*, 1990*a*]; and Ontario Pharmacists' Association [1988*b*].

36 For discussion of instances where pharmacists can improve outcomes, see United States Department of Health and Human Services [1990*a*, 7-8]; Cureton and Jay [1990, 6-3 and 6-4]; Task Force on the Cost-Effectiveness of Pharmaceutical Products and Pharmacy Services [1989, 39]; and Hepler and Strand [1990, 538]. For an interesting example of trying to design a professional component index that relates the professional input as a function of the medicine and the patient, see Bell et al. [1990]; and Lloyd and Stock [1990].

37 See also United States Department of Health and Human Services [1990*a*, 19].

38 There is little incentive not to fill a prescription when extra paperwork is required, but the reimbursement is the same. Written suggestions to the physician probably require considerable effort on the part of the pharmacist for a return of less than $10.

39 There are also other barriers. See, for example, the discussion in United States Department of Health and Human Services [1990*a*, 10-16].

40 Indeed, this may result in specialist pharmacies devoted almost exclusively to providing these services. For a discussion of so-called boutique pharmacies, see Johnston [1987].

41 In Ontario, pharmacies can only be owned by pharmacists or corporations in which pharmacists have a majority of each class of shares and are a majority of the board of directors (Sections 138 and 140 of the Health Disciplines Act R.S.O. as amended 1983, 1986). However, these conditions do not apply to corporations that have been operating pharmacies since before 1954 (Section 138 (4)). Indeed, there is a market for pre-1954 pharmacy charters, so non-pharmacists can own pharmacies (e.g., see the advertisement in the *Canadian Pharmaceutical Journal*, November 1989, p. 628). The Ontario College of Pharmacists and the Ontario Pharmacists' Association tried unsuccessfully to get this latter provision removed from the legislation in 1970. In rejecting their demand, the Ontario Committee on the Healing Arts said:

> Our studies suggest to us that the pharmaceutical industry has not been marked by strong elements of commercial competition; rather, the industry has tended to be one in which restricted entry to the trade has economic implications which may be contrary to the best interests of consumers. Thus we are not disposed to recommend steps which might further limit competition in this field, nor have we heard any evidence that the pre-1954 corporate charters have been abused. It is not desirable to interfere with existing vested rights unless there is a clear reason to do so. Therefore, we do not recommend cancellation of these existing charters, but only constant review of the situation by the Department of Health [1970, vol. 2, 241].

In the United States, the fastest growing segment of retail distribution of drugs is in food and drug combinations [Cureton and Jay 1990, 4-1]. These are also of increasing importance in British Columbia.

42 On the British Columbia case, see *R. vs. B.C. Professional Pharmacists' Society et al.* (1971) 1 W.W.R. 705, 3 C.C.C. (2*d*) 29, 17 D.L.R. (3d) 285, 64 C.P.R. 129; on the Ontario case, see *R. vs. Metropolitan Toronto Pharmacists' Association* (1984) 3 C.P.R. (3*d*) 233; on the Nova Scotia case, see Director of Investigation and Research [1989, 61]; and on the Quebec case, see McKenna [1990]; and court documents for the Nova Scotia and Quebec cases. The Crown was not successful in its prosecution of the Metropolitan Toronto Pharmacists' Association (see Chapter 3). The Nova Scotia and Quebec cases are still before the courts (the charges were only laid in August and April 1990, respectively; although in the case of Nova Scotia, the original summonses were sworn in February 1987). The Crown is experiencing considerable difficulty because of challenges pursuant to the Charter of Rights and Freedoms.

43 Even in Newfoundland the fee is negotiated between the government and the Provincial Pharmacy Association, except for seniors who receive the Guaranteed Income Supplement.

44 For a discussion of other forms of copayment, see Hurley [1989, 60-67, 70-84]; and also Chapter 2 of the present study.

45 For example, it is assumed that there is no *additional* wastage of unused drugs because of increased quantities per claim. Therefore, careful monitoring will be required, perhaps combined with something along the lines of the B.C. trial prescription program described above, to gauge how important such additional wastage might be.

46 However, as Hurley notes, the elasticities used to estimate the impact of the copayment have to be taken from other countries in situations that do not match closely the situation in Ontario, so the estimates he presents are only "ballpark" figures [1989, 102-3].

47 The mixture between these two effects is not exogenous, but to a considerable degree endogenous. If the ODB informs patient/consumers that larger quantities can be prescribed and dispensed, abolishes rules on fee disclosure and the monetary incentives that encourage physicians to require patient/consumers to come in person to renew their prescriptions every month, then quantity dispensed per claim is more likely to increase, and demand for drugs is less likely to decrease.

48 The literature on the impact of copayments could be consulted in designing such a monitoring program. See, for example, Soumerai et al. [1987]; Nelson et al. [1984]; Maritime Medical Care [1991]; and Reeder and Nelson [1985].

Chapter 5

1 For details of this see Ontario Drug Benefit Act of 1986, Sections 16 (1) and 18 (2) and Ontario Regulation 689/86, Section 12. The formulary is actually issued under the authority of the Lieutenant Governor in Council.

2 These are specified in Ontario Regulation 689/86, Section 4. Prompt payment within 30 days of the sale of the product to the pharmacy can result in a discount of 2 per cent of the net price of the product without the BAP being affected. A manufacturer can delay payment for up to 120 days without this being considered a discount and without the BAP being adjusted.

3 Letter to Ontario pharmacists dated 20 February 1991 from Yale S. Drazin, director of the ODB. See also Archer [1991, 114].

4 Quebec, whose provincial drug reimbursement system is similar to Ontario's, is also recovering moneys from pharmacists due to the spread, but only for those six drugs which are priced on an AAC basis.

5 In the case of over-the-counter products, the BAP includes a 33.3-per-cent mark-up on the product price in lieu of a dispensing fee. In the case of products distributed 51 per cent or more through a wholesaler, the product price includes a 10-per-cent add-on. In all other instances there is no automatic add-on.

6 The reverse is not true. If there was another brand of mebendazole which was not in the formulary, the pharmacist, on receiving a prescription for it, could apparently dispense Vermox instead (Prescription Drug Cost Regulation Act of 1986, Section 4 (5)).

7 These findings were confirmed by the author in a number of meetings with industry personnel, both from the generic and innovative sectors.

8 Table 7-1 also shows that the average cost of single-source drugs per claim rose between January-June 1986 and January-June 1987, but by 29.4 per cent.

9 In one instance there was only one brand listed in Saskatchewan, while in the other two, although they were interchangeable in Saskatchewan, there was no SOC.

10 In order to test this, the following variable was estimated: 1 – (Ontario price/Saskatchewan price). A signed rank test could not reject the null hypotheses that the central tendency was significantly different from zero.

11 Prices for these drugs were reduced in Ontario with the introduction of the BAP in 1986. For the six drugs in panel A, the mean of the ratio of the lowest-priced brand for 1987 to 1986 was 59.75; for 1989 to 1987 it was 95.09. These comparisons were estimated using the approach in Table 5-3.

12 This was also confirmed in conversations with a number of industry and pharmacy representatives. See also Ontario Ministry of Health [1988*b*, 4-5]; and Archer [1991, 114].

13 For further discussion of the 10-per-cent margin, see Gorecki [1990*a*, Chapter 4, 52-53, 67-70]. The Pharmaceutical Inquiry of Ontario [1990*a*, 77-84] comes to a similar conclusion but suggests that the reduced mark-up on the BAP – the 10 per cent – should be reflected in an increase in the fee. In our view this is inappropriate.

14 On New Brunswick's experience, see New Brunswick Commission on Selected Health Care Programs [1989, 73-78].

15 However, it will only reimburse for drug products manufactured by companies that are participants in the Drug Quality Assurance Program, details of which may be found in Chapter 3. The plan also has a list of eligible benefits.

16 This assumes that the pharmacist can product select. In other words, the low-priced brand is not prescribed, and the physician has not specified that the high-priced brand must be dispensed.

17 These values are taken from Gorecki [1986*c*]. The ratio of P_p to P_1 was 2.89 [Table 13, 116], while e was the patentee market share in British Columbia [Table 9, 112]. Note that this was before the introduction of the BAP, but as discussed in Chapter 3 of the present study, this system was in many important respects similar to the BAP.

18 Medicare and Medicaid in the United States recently introduced incentives to encourage greater market penetration by lower-priced brands [Professional Management Associates 1987; United States Federal Register 1987].

19 This section is based on Anderson [1989, 1990]; Anis [1989, 53-90]; Pharmaceutical Manufacturers Association of Canada [1988*a*]; Nova Scotia Department of Health [1990, 47-48]; Nova Scotia Royal Commission on Health Care [1989]; Gorecki [1986*c*]; *Pharmacists' Bulletin*; and discussions with officials of Nova Scotia Pharmacare.

20 The $0.40 and $0.50 premiums suggest that pharmacies respond to either very large or very visible price differentials. Pharmacare suggested that one reason that the product selection rate was not higher in the pre-AAC period, even though there was a spread, was that too much effort was required on the part of pharmacies to detect hidden markups on individual products.

21 This section is based on Anderson [1989, 1990]; Strong and Harvey [1989]; Gorecki [1986*c*, 60-62]; *Mittee III* [various issues]; and data and documentation supplied by B.C. Pharmacare.

22 Pharmacare did a special audit of a quantity rebate offered by Smith, Kline and French Canada on its Ecotrin products purchased between 26 September and 25 November 1983. When pharmacists agreed in the mid-1980s to increase product selection of lower-priced brands, several manufacturers offered cash and merchandise rebates in order to retain brand loyalty. In 1988 fax machines were offered to pharmacists. In the late 1970s some pharmacists considered setting up "dummy" wholesale operations for the purposes of obtaining profits on drug purchases [*Mittee III*, various issues]. In 1986 cash rebates and other gifts such as silver ingots and subsidized trips to Paris were investigated [Canadian Press 1986].

23 See, for example, Gorecki [1986*c*, 90, footnote 121].

24 The most notable exception is the glyburide 5-mg tablet. Both brands of this drug are made by brand-name manufacturers, and there is very little difference in price between the two brands. Competition is therefore likely to be primarily nonprice.

25 However, if the major generic firms – Novopharm, Apotex, ICN, and Horner – are in Ontario, they are usually in British Columbia as well.

26 This is consistent with Strong and Harvey [1989], who compare the 1988 AAC prices of the top 60 brands in British Columbia with the BAPs in the Ontario formulary of July 1989. For the B.C. sample, the dosage form and strength of a given brand was listed as a separate entry. The ranking was on the basis of the number of prescriptions paid for by Pharmacare in 1988.

27 Strong and Harvey [1989] estimate for 1988 that the Ontario BAP system pays lower prices than does the AAC system.

28 B.C. Pharmacare does not, of course, certify two brands of the same drug as interchangeable, but it did issue price lists for the PIP in which all brands of the same drug were grouped together.

29 Market size is measured in Table 5-9 by number of prescriptions; in Table 5-8 it is measured by number of tablets or capsules. This use of different units of measurement does not change the conclusions.

30 The prices of eight of the 14 higher-priced brands increased continuously between 1990 and 1991, the prices of five fell, and the price of one remained constant in one of the two periods immediately following the introduction of the PIP, before they all resumed their upward trend.

31 Even for the market share that is retained, the price charged is frequently that of the product with the lowest BAP listed.

32 For details of the Saskatchewan system, see Saskatchewan Health Prescription Drug Plan [1984, 1987, 1988]; and on one hospital buying group – Hospital Purchasing Incorporated of Toronto – see Gorecki [1986*c*].

33 These profitability measures were for 1987 and appear in a draft copy of a report by the Ontario Ministry of Industry, Trade and Technology [1991]. The report also demonstrates that the generic and brand-name sectors of the pharmaceutical industry have rates of return well above the all-manufacturing average. Thus if there is a problem with high rates of return, it is with the industry as a whole, not just the generic sector.

Chapter 6

1 The success of these strategies will be at the expense of the generic brands. Therefore, we examined the briefs presented by the generic drug manufacturers to the Pharmaceutical Inquiry of Ontario on brand-name strategies. See, for example, Apotex [1988]; Canadian Drug Manufacturers Association [1988, 1989]; and Novopharm [1988].

2 On arguments used in the 1960s and 1970s, see Ferguson et al. [1973]; Gorecki [1981, 1986*b*]; and Chapter 3 of the present study. On arguments put forward in the 1980s and 1990s, see Canadian Drug Manufacturers Association [1989]; Novopharm [1988]; and Chapter 7 of the present study.

3 See, for example, *Apotex Inc. vs. Syntex Inc.*, Federal Court of Appeal, J. A. Heald, 8 May 1991; and *Novopharm Ltd. vs. Syntex Inc.*, Federal Court of Appeal, J. A. Heald, 8 May 1991; both unreported judgments.

4 On the PC-34 form the physician is required to supply the patient's name, the name, strength, and quantity of the drug, and directions for its use. The physician is not required to justify the use of a PC-34 form. In the non-ODB market there might be fewer bureaucratic procedures, which could explain why the no-substitution rate is higher in that market. A survey of 200 pharmacies undertaken for Upjohn by Market Facts of Canada [1988, 35] found that the overall Ontario

no-substitution rate in 1988 was 6.65 per cent. However, officials at the Ministry of Health suggested that only approximately 50 per cent of no-substitution claims are recorded. Even so, the non-ODB no-substitution rate is still substantially above that recorded for the ODB.

5 This was derived by taking the average cost of "special" claims, which include both no-substitution prescriptions and special authorizations, deducting the average dispensing fee, and multiplying the answer by 472,849. The average cost of a special claim in 1988/89 was more than twice a regular ODB claim.

6 These proportions are based on estimate A in Table 6-2. If estimate B is used instead, the proportions are 0.38 and 0.63, respectively.

7 In July 1990, on the recommendation of the New Brunswick Commission on Selected Health Programs [1989], New Brunswick stepped up its educational program on interchangeability and also established a maximum allowable price that the program would pay for an interchangeable product. However, in the three months after this change, in 3 per cent of the claims the physician provided sufficient justification for the government to pay for a no-substitution prescription, while in another 3 per cent of the claims the patient/consumer paid the difference between the government-determined lowest price for an interchangeable drug and the patient's preferred brand (data supplied by the New Brunswick Drug Program).

8 As of April 1991, for those aged 65 and over, the Newfoundland drug program pays only for the lowest-cost interchangeable brand; patient/consumers who want a more expensive brand have to pay for it themselves.

9 Before 1990 in New Brunswick and 1991 in Newfoundland, the provincial drug programs paid for a no-substitution prescription when the physician wrote "no substitution" on the prescription.

10 Although it is apparently illegal to ship prescription drugs from Canada to the United States, when Tagamet lowered prices in the early 1980s in the face of generic competition, there were reports of the brand-name drug being shipped across the border.

11 It is not clear that as a long-term strategy it was a feasible option. Generic-drug manufacturers do not have to incur many of the costs that brand-name drug manufacturers necessarily incur, such as the costs of discovering the drug, the regulatory costs of obtaining a Notice of Compliance (proof that the health and safety requirements to sell the drug in Canada have been met), the costs of building a market by extensive marketing through detail persons and advertising in medical journals, and the cost of the raw material purchased from the firm's foreign parent. In contrast, generic-drug manufacturers have to complete far fewer regulatory requirements to obtain a Notice of Compliance and gain admission to the formulary. The market for the generic firm's product is created by a combination of the marketing efforts of the brand-name firms and the ODB price and product selection rules that virtually compel selection of the lower-priced brand. Finally, generic-drug manufacturers buy their active ingredients on the open world market.

12 However, the evidence to the early 1980s did not suggest a shortening of the period of market exclusivity for the brand name [Commission of Inquiry on the Pharmaceutical Industry 1985, 350-51].

13 The generic-drug manufacturers use the term "pseudo-generics" [Canadian Drug Manufacturers Association 1988, 1989]. Ultragenerics is the trademark of the fighting brands sold by Syncare.

14 The marketing of fighting brands is not confined to Ontario; it also takes place in other provinces.

15 The entry date for ketoprofen in the table is July 1990, rather than January 1989. This reflects the fact that frequently there will be more than one strength of a fighting brand listed in the formulary. In Table 6-5 the highest-dollar-volume strength is used. Typically all strengths are listed in the formulary at the same time. However, ketoprofen was an exception to this rule.

16 The remainder of this section is based on discussions with one firm that markets fighting brands and the Canadian Drug Manufacturers Association [1991*b*].

17 On average, among interchangeable drugs in Ontario, when there is one generic brand, its price is 80 per cent of the brand name; for three generic brands the ratio of the lowest-priced drug to the brand name is about 60 per cent; and for five generic brands, the ratio is 40 per cent [Canadian Drug Manufacturers Association 1991*a*].

18 There is an exception – the discount offered by Rhodiapharm's two brands of Rhodis-EC, which was set at 61 per cent of the brand-name price, much lower than the discount on any generic drug. Apparently Rhodiapharm was expecting Apotex to market a generic brand to compete with Rhodis-EC, but it did not. As a result Rhodiapharm apparently had a temporary difficulty supplying the market, which was much larger than it anticipated. Rhodiapharm could have followed an alternative pricing strategy, if it expected a generic brand to come onto the market but was unsure in which formulary it would appear. It could have set the Rhodis-EC price close to the brand name. If the generic brand appeared, Rhodiapharm could then inform the ministry of the new lower price.

19 Kenral said that it would "match" the generic competitor's BAP for triazolam [Canadian Drug Manufacturers Association 1989, Appendix IV].

20 It may be, of course, that although the fighting brand loses the SOC, it nevertheless forces the price to fall substantially. Panels A and B of Table 5-5, however, show that SOC prices seem to have reached a plateau between 1989 and 1990, rather than declining continuously.

21 Of course, given that interchangeable drugs cost less than single-source drugs, it is unlikely they would command such a position in terms of sales.

22 For details of the law and literature on predatory pricing, see McFetridge and Wong [1985]; and OECD [1989].

23 In the Ontario formulary of July 1990, all the long-acting dosage forms of diltiazem are listed under both cardiac drugs and hypotensive drugs; the two long-acting dosage strengths of nifedipine are listed under hypotensive drugs only and the immediate-release dosage forms are listed under cardiac drugs only; and one long-acting dosage form of verapamil is listed under hypotensive drugs only and the two immediate release strengths under cardiac drugs only. In the January 1989 formulary the long-acting dosage forms of all three drugs are listed only under cardiac drugs, in the same category as the immediate-release dosage forms.

24 Based on two memoranda from the Executive Director, Saskatchewan Prescription Drug Plan. The first, dated 20 February 1991, addressed to all Saskatchewan pharmacies and distributors and all manufacturers was titled "Changes to the Saskatchewan prescription drug plan"; the second, dated 20 March 1991, addressed to pharmacies, wholesalers, manufacturers, and physicians was titled "Sustained-release products."

Chapter 7

1 A separate product is defined as one having a unique drug identification number, given to it by the Health Protection Branch of the Department of Health and Welfare. A separate number is given for different dosage forms and strengths of a drug and for each brand of each manufacturer. Reformulation of a drug by a manufacturer can result in a new number for that drug. Thus the total number of separate drugs is lower than the number of drug identification numbers.

2 In a 1989 survey of Ontario physicians one quarter cited the rate of introduction of new drugs as a serious problem that prevented them from keeping up with professional knowledge about prescription drugs [Williams and Cockerill 1989, 40, and Table 5.3, 47]. This factor was also identified by Carruthers et al. [1987, 244] as one of five leading to inappropriate prescribing by physicians.

3 This does not mean, of course, that physicians and patient/consumers collectively or individually, in some ideal state, do not have an interest in more cost-effective prescribing. Failure to do so may result in expense to patient/consumers, which will adversely affect their welfare, and restrictions on the freedom of physicians to prescribe as they see fit, which will in turn adversely affect their welfare.

4 Williams and Cockerill [1989, 29-30] report, for example, that "the frequency of physician contacts with pharmaceutical companies increases significantly with prescription volume. For instance, physicians writing more than 70 prescriptions per week report the highest frequency of contact with 'detail men.'"

5 The duties, organization, and procedures are detailed in administrative guidelines. They also include conflict of interest provisions. Furthermore, members are asked to avoid public presentations about the DQTC to drug manufacturers and pharmaceutical associations "so as not to create any appearance of unfairness on the part of Committee members" [Ontario Ministry of Health 1989*b*, 5]. A very brief overview of the activities of the DQTC may be found in Carruthers [1986].

6 For details see *Apotex vs. Attorney General Ontario, Minister of Health and Lieutenant Governor in Council*, J. Rosenberg, Supreme Court of Ontario, unreported judgment, 5 July 1984.

7 For example, Apotex's ibuprofen was delisted from the Ontario formulary in 1986 [Apotex 1988]. Saskatchewan adopted a different approach. It retained Apotex's brand in the formulary as interchangeable and listed the concerns over its interchangeability. See, for example, Saskatchewan Department of Health [1986, 43].

8 The time it takes to list drugs in Ontario differs little from other provinces, at least for generic brands [Gorecki 1986*a*, Table 1, 378-79].

9 At the present time a DQTC member who has a pecuniary interest in a matter under consideration before the committee is obliged to disclose this to the chairman of the committee and not participate in the DQTC's deliberations on the matter. Members are to avoid contact with drug manufacturers on pending submissions and issues. They are also required to sign an Acknowledgement and Statement of Confidentiality, which simply says that the member has read the relevant parts of the administrative guidelines. For further details of these guidelines, see Ontario Ministry of Health [1990*c*].

10 This model requires disclosure of work undertaken for the pharmaceutical industry and financial interests and limits the portion of the member's income that can be obtained from the pharmaceutical industry for a year before and after membership [Canada Department of Health and Welfare 1989*b*].

11 For further discussion of the role of cabinet in regulatory agencies, see Economic Council of Canada [1979, 63-68].

12 Such information is likely to be underprovided by the market.

13 This would seem a much better alternative than compelling generic drug firms to "publicize appropriate information to prescribers, as innovative manufacturers now do" as suggested by the Pharmaceutical Inquiry of Ontario [1990*a*, 48].

14 Strictly speaking, this report does not apply to the DQTC. Its mandate covers agencies that make decisions, rather than

those that give advice. Nevertheless, the general approach and tenor of the report seems also to apply to agencies such as the DQTC.

15 Only special authorizations for drugs are dealt with in this study. In Pharmaceutical Inquiry of Ontario [1988*b*] the tables also include allergens and oxygen, which are not discussed here because the DQTC does not deal with them.

16 The sample was selected from the Ontario Drug Benefit, "Formulary utilization," computer printout, March 1986. The monthly values were multiplied by 12 to derive the annual values. All brands and dosage forms of a given drug were grouped together.

17 Other interim benefits include drug products used "where no appropriate alternative may exist in the current Formulary; in the treatment of uncommon diseases; mainly for use in hospitals but in rare circumstances may be used in home care therapy" [Ontario Ministry of Health 1989*d*, 3].

18 An expert review is to be undertaken to examine the product documentation for interim benefits; to establish the appropriate indications for use and the merits of each product for these indications of nutritional supplements; and to carry out an overall review of moisturizers, vehicles, and bases [Ontario Ministry of Health 1989*d*, 5].

19 However, the Pharmaceutical Inquiry of Ontario [1990*a*, 46] writes that in 1990 "many of the highly reimbursed products which were intended to be eliminated, persist." Since the identity of these products was not revealed it is not possible to state whether they have been subsequently eliminated.

20 See also Apotex [1988] concerning the use of experts by the same brand-name firm over the interchangeability of ibuprofen.

21 In January 1989 the Canadian Drug Manufacturers Association and two generic drug manufacturers launched a $325-million suit against the Ontario Medical Association, the Upjohn Company of Canada, the video production company, and the eight doctors who participated in the video. The suit claims that the video is "misleading and calculated to undermine the confidence of health-care professionals and consumers in generic drugs." The case is still before the courts [late 1991]. For details of the suit, see McQuaig [1989]. More recent information was provided by the Canadian Drug Manufacturers Association.

22 In 1984, legislation was passed in the United States that expedited approval of generic drugs. This led to some brand-name manufacturers challenging the generic firms. In response to this, the FDA listed 10 charges or myths raised by brand-name firms [Novopharm 1988].

23 In the index of drugs by therapeutic classification in the Ontario formulary, anticonvulsants are code 28:12 and cardiovascular drugs are code 24:00. The no-substitution rates were calculated using number of claims. The data are taken from Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989.

24 As such it appears to be inconsistent with the Pharmaceutical Inquiry of Ontario [1990*a*, 47], which appears to endorse the Ontario Medical Association's stand.

25 Gorecki [1986*c*, Table 6, 109]; and Ontario Drug Benefit, "Formulary utilization," computer printout, March 1989.

26 There are several possible reasons why patient/consumers might express a preference for the brand-name product. They might wish to support the brand-name firm's R&D, perhaps influenced by the extensive media campaign by the Pharmaceutical Manufacturers Association of Canada on behalf of brand-name firms. The 1990/91 campaign included a newspaper advertisement that read "Bringing research to life" (e.g., *The Globe and Mail*, Report on Business, Toronto, 19 September 1990, p. B7) as well as a TV commercial in a similar vein. The TV commercials were still being aired in late 1991. For details see *Scrip*, no. 1554, 3 October 1990, p. 20.

Or, since advertising is allowed for over-the-counter products, they might prefer the brand-name product as a result of such advertising. When one strength of ibuprofen changed from prescription to over the counter, the newspaper advertisement showed 16 prescriptions, all with the words "no substitution" written across them. The dates on some of the prescriptions predated the arrival of a generic competitor of ibuprofen (see, e.g., *The Globe and Mail*, 10 January 1990, Toronto, p. A3).

27 For details see Soumerai et al. [1989]; United States Office of Technology Assessment [1980*a*, 1980*b*]; Carruthers et al. [1987]; and Pharmaceutical Inquiry of Ontario [1990*a*].

28 See, for example, Doubilet et al. [1986]; Dao [1985]; Weinstein and Stason [1977]; Drummond et al. [1988]; Task Force on the Cost-Effectiveness of Pharmaceutical Products and Pharmacy Services [1989]; and United States Office of Technology Assessment [1980*a*, 1980*b*].

29 A new drug product is one with a separate drug identification number. The numbers are given for different dosage forms and strengths of a drug, even when marketed by the same firm. The Patented Medicine Prices Review Board [1991, 9] also describes the three categories of drugs in more detail. See also the discussion in Commission of Inquiry on the Pharmaceutical Industry [1985, 237-43].

30 The Commission of Inquiry on the Pharmaceutical Industry felt that there could be difficulties in implementing the model in Ontario because there "may not be enough pharmacists with the necessary training and skills" [1985, 111]. However, as the discussion in Chapter 4 suggests, it is by no means clear that such a shortage exists in Ontario.

31 See, for example, Rucker [1983]; and United States Department of Health and Human Services [1989, 1990*c*].

32 Soumerai et al. [1989, 282-84] summarize the literature.

33 See Hlynka and Danforth [1981]; Hlynka et al. [1981]; and Danforth et al. [1982] who describe the design of the DUR and its implementation in an ambulatory and long-term care setting.

34 See Schnell [1981]; and Blackburn et al. [1990].

35 Carruthers et al. [1987, 250-52]; and Pharmaceutical Inquiry of Ontario [1990*a*, 160-61].

36 See the earlier discussion of the peer review conducted by the college and the role of the college in assuring and monitoring quality. See also Mickleburgh [1991].

List of Tables and Figures

Tables

1-1	Public and private per-capita expenditure on prescription drugs, Canada and the provinces, selected years, 1975-87	2
1-2	Public-sector expenditure as a proportion of total expenditure on prescription drugs, Canada and the provinces, selected years, 1975-87	5
1-3	Drug costs, dispensing fees, and number of claims for persons aged 65 and over, selected provincial drug reimbursement programs, 1987	8
2-1	Breakdown of expenditure on claims by the Ontario Drug Benefit, 1979/80 to 1987/88	10
2-2	Distribution of ODB eligible and beneficiary populations, by plan type, 1981/82 to 1988/89	12
2-3	The age structure of the population, Ontario, 1986 and 1996 (projected)	13
2-4	Prescription drug utilization by age, Saskatchewan, 1986/87	13
2-5	Expenditure under the Ontario Drug Benefit, 1979/80 to 1987/88	17
4-1	Number of claims and average quantity dispensed per claim for 40 high-volume drugs under the Ontario Drug Benefit, before and after the introduction of a dispense-as-written policy, 1986-89	40
4-2	Level and ratios of the average quantity dispensed per ODB claim for 40 high-volume drugs, 1986-89	42
4-3	A comparison of average quantity dispensed per claim of 35 high-volume drugs, Ontario Drug Benefit and B.C. Pharmacare, before and after B.C. Pharmacare introduced a copayment on dispensing fees for seniors, 1986-89	43
4-4	The structure of private and public dispensing fees in the retail drug market, Ontario, 1987-91	45
4-5	Distribution of ODB claim payment among retail pharmacy stores, August 1985 to January 1986	48
4-6	Estimated impact of various fee-setting mechanisms on ODB expenditure, 1988/89	56
5-1	An example of pricing and other information on interchangeable, noninterchangeable, and single-source drugs in the Ontario formulary, 1989	61
5-2	Short-run and long-run impact of the BAP on the 10 highest-dollar-volume single-source and interchangeable drugs under the Ontario Drug Benefit, 1986, 1987, and 1989	62
5-3	Average change in ODB prices of the 10 highest-dollar-volume single source and interchangeable drugs, 1986-89	63
5-4	A comparison of formulary prices for the highest-dollar-volume interchangeable drugs, Ontario and Saskatchewan, January-June 1989	64
5-5	A comparison of formulary prices for interchangeable drugs for which there is a fighting brand, Ontario and Saskatchewan, 1989 and 1990	65
5-6	Estimates of the spread on the ODB prices of interchangeable drugs, July 1990 to February 1991	67

5-7 The impact of various policy changes on Nova Scotia Pharmacare's drug costs, and the market share of generic drug manufacturers, selected periods, 1983-90 74

5-8 Drug prices and market shares, B.C. Pharmacare and Ontario Drug Benefit, highest-dollar-volume interchangeable drugs, 1989 75

5-9 The impact of the product incentive plan on drug prices and market shares of lower-priced brands, highest-dollar-volume interchangeable drugs, B.C. Pharmacare, 1990-91 78

5-10 Lag between the formulary listing of the first and second lower-priced interchangeable brands of the highest-dollar-volume interchangeable drugs, Ontario Drug Benefit, 1975-91 80

6-1 Number of no-substitution claims under the Ontario Drug Benefit, 1981-89 84

6-2 The importance of no-substitution prescriptions among the highest-dollar volume interchangeable drugs, Ontario Drug Benefit, 1989 85

6-3 The importance of various factors in accounting for the changing level of no-substitution claims for the highest-dollar-volume drugs, Ontario Drug Benefit, March 1987-89 86

6-4 No-substitution claims among the highest-dollar-volume interchangeable drugs for which those claims exceeded 4 per cent of ODB expenditure on the drug, March 1987 and 1989 87

6-5 Price ratios and competitors of fighting brands, and date fighting brand was first listed in Ontario formulary, 1984-91 90

6-6 Distribution and market shares of brand names, fighting brands, and generic brands of the 32 highest-dollar-volume drugs, Ontario Drug Benefit, 1989-91 91

6-7 Ratio of the Ontario formulary price of the first lower-priced interchangeable brand listed to that of the brand-name drug for cardiovascular and central nervous system drugs, 1989-91 93

6-8 Market shares and price ratios of interchangeable drugs with fighting brands and generic brands, by marketing company, ODB formulary, March 1989 94

6-9 Market shares of brand names, fighting brands, and generic brands of interchangeable drugs over a three-year period, Ontario Drug Benefit, 1989-91 96

6-10 Firms awarded standing offer contracts to supply drugs for which there was a fighting brand, by marketing firm, Saskatchewan, 1985-91 98

6-11 Market shares and price ratios of interchangeable drugs with fighting brands and generic brands, by marketing firm, Nova Scotia Pharmacare, 1990 100

6-12 Market shares and number of strengths of long-acting and immediate-release dosage forms of the highest-dollar-volume drugs, Ontario Drug Benefit, 1989-90 102

7-1 Single-source and interchangeable drugs in the Ontario formulary, 1979-88 108

7-2 The status of the 32 highest-dollar-volume drugs, Ontario Drug Benefit, March 1979 and 1989 109

7-3 Number of drug products considered by the DQTC for inclusion in the formulary, Ontario, 1989 114

7-4 Special authorizations as a proportion of the number and value of all claims paid for by the Ontario Drug Benefit, 1986-89 119

7-5 Distribution of claims for, and cost of, H_2 receptor antagonists, Ontario Drug Benefit, March 1986 and 1989 126

Figures

1-1	Public health-care expenditure as a proportion of total health-care expenditure, and public expenditure on drugs as a proportion of total expenditure on drugs, Canada, 1970-87	3
1-2	Prescribed drugs as a proportion of public and private health expenditure, Canada, 1970-87	4
1-3	Coverage and copayment under provincial drug reimbursement programs, 1989	5
1-4	Provincial drug reimbursement programs: copayment mechanisms, persons aged 65 and over, 1989	6
1-5	Provincial drug reimbursement programs: models for setting drug prices, 1989	6
2-1	Proportion of the eligible population that are drug plan beneficiaries ($\propto$), by age group, Saskatchewan, 1983/84 and 1986/87	14
2-2	Average number of prescriptions per beneficiary ($\bar{q}$), by age group, Saskatchewan, 1983/84 and 1986/87	15
2-3	Proportion of the eligible population that are drug plan beneficiaries ($\propto$), by age group, Quebec, 1983 and 1989	16
2-4	Average number of prescriptions per beneficiary, by age group, persons aged 65 and over, Quebec, 1983 and 1989	16
2-5	Components of the increase in the 1987/88 in ODB expenditure over 1981/82 expenditure	16
4-1	How pharmacists' dispensing fees are determined under the Ontario Drug Benefit Act of 1986	38
4-2	Models and mechanisms for compensating pharmacists	50
4-3	Average monthly number of claims by number of persons, Ontario Drug Benefit, 1988/89	53
6-1	Number of monthly claims for various dosage forms of the highest-dollar-volume drugs, Ontario Drug Benefit, March 1986 to March 1991	104
7-1	The drug submission process for inclusion in the Ontario formulary	113

Glossary and Abbreviations of Dosage Forms

AAC	Actual acquisition cost
BAP	Best available price
CDI	Comparative Drug Index
CDMA	Canadian Drug Manufacturers Association
CPI	Consumer price index
DBF	Drug Benefit Formulary
DIN	Drug identification number
DQTC	Drug Quality and Therapeutics Committee
DUR	Drug utilization review
FDA	Food and Drug Administration
FNC	Fee Negotiation Committee
IMS	Intercontinental Medical Statistics
MAC	Maximum allowable price
MAP	Market assessed price
ODB	Ontario Drug Benefit
OMA	Ontario Medical Association
OPA	Ontario Pharmacists' Association
OTC	Over-the-counter [drugs]
PAAB	Pharmaceutical Advertising Advisory Board
PARCOST	Prescriptions at reasonable cost
PBP	Product base price
PIP	Product incentive plan
PMAC	Pharmaceutical Manufacturers Association of Canada
SOC	Standing offer contract

Abbreviations of Dosage Forms

Aero.	Aerosol
Ent.	Enteric
HCl	Hydrochloride
Inh.	For inhalation
LA	Long acting
O/L	Oral liquid
Oph.	Ophthalmic
Oral pd.	Oral powder
Pd.	Powder
Sol.	Solution

Bibliography

Advisory Council on Adjustment [1989]. *Adjusting to Win*. Ottawa: Supply and Services Canada.

Alberta. Premier's Commission on Future Health Care for Albertans [1989]. *The Rainbow Report: Our Vision for Health*. Edmonton: Premier's Council.

American Medical Association [1986]. *Drug Evaluations*. 6th edition. Milwaukee, Wisconsin: AMA.

Anderson, Lori J. [1989]. *Provincial and Territorial Drug Reimbursement Programs: Descriptive Summary*. Bureau of Pharmaceutical Surveillance, Drugs Directorate, Health Protection Branch. Ottawa: Health and Welfare Canada.

_____ [1990]. *Provincial and Territorial Drug Reimbursement Programs: Descriptive Summary*. Bureau of Pharmaceutical Surveillance, Drugs Directorate, Health Protection Branch. Ottawa: Health and Welfare Canada.

Anis, Aslam H. [1989]. "Essays on the effects of government policy on firm and industry behaviour." Unpublished Ph.D thesis, Carleton University, Ottawa.

Anonymous [1986]. "Discounting discouraged in Saskatchewan." *Canadian Pharmaceutical Journal* 119, no. 9 (September):482.

Aoki, F. Y., et al. [1983]. "Aging and heavy drug use: a prescription survey in Manitoba." *Journal of Chronic Disease* 36:75-84.

Apotex Inc. [1988]. "Submission to the Pharmaceutical Inquiry of Ontario." Weston, Ontario.

Archer, D. G. [1979]. *Annual Report of the Provincial Auditor of Ontario for the Year Ended March 31, 1979*. Toronto: Queen's Printer.

_____ [1984]. *Annual Report of the Provincial Auditor of Ontario for the Year Ended March 31, 1984*. Toronto: Queen's Printer.

_____ [1991]. *Annual Report of the Provincial Auditor of Ontario for the Year Ended March 31, 1991*. Toronto: Queen's Printer.

Astra Pharma Inc. [1988]. "A presentation to the Pharmaceutical Inquiry of Ontario." Mississauga, Ontario.

Australia. Bureau of Industry Economics [1985]. *Retail Pharmacy in Australia: An Economic Appraisal*. Research report no. 17. Canberra: Australian Government Publishing Service.

Avorn, Jerry, et al. [1982]. "Scientific versus commercial sources of influence on the prescribing behavior of physicians." *American Journal of Medicine* 73 (July):4-8.

Avorn, Jerry, and Stephen B. Soumerai [1983]. "Improving drug-therapy decisions through educational outreach: a randomized controlled trial of academically based 'detailing.'" *New England Journal of Medicine* 308, no. 24 (June 16):1457-63.

Bailey, Knowles, et al. [1978]. "Report of the Ontario Drug Benefit Formulary Pricing Committee." Ministry of Health, Toronto.

Barer, M. L., et al. [1979]. *Controlling Health Care Costs by Direct Charges to Patients: Snare or Delusion?* Occasional Paper 10. Toronto: Ontario Economic Council.

Barer, M. L., et al. [1988]. "Fee controls as cost control: tales from the frozen north." *Milbank Quarterly* 66, no. 1, pp. 1-64.

Bell, John, et al. [1990]. "Society moves to establish new basis for remuneration." *Australian Pharmacist* 9, no. 4 (August): 99-100.

Bertrand, Robert J. [1981]. *The State of Competition in the Canadian Petroleum Industry*. Ottawa: Supply and Services Canada.

Blackburn, Jim L., et al. [1990]. "The Saskatchewan program for rational drug therapy: effects on utilization of mood-modifying drugs." *DICP, The Annals of Pharmacotherapy* 24, no. 9 (September):878-82.

Blackhurst, Chris [1989]. "In search of the global prescription." *Sunday Times* (London), 30 April, pp. D10-D11.

Boehringer Ingelheim (Canada) Ltd. [1988]. "A presentation to the Pharmaceutical Inquiry of Ontario." Burlington, Ontario.

Bond, Ronald S., et al. [1980]. *Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*. Economic staff report, Federal Trade Commission. Washington, D.C.: U.S. Government Printing Office.

British Columbia. Royal Commission on Health Care and Costs [1991]. *Closer to Home*. Victoria: Crown Publications.

Brown, Ruth E., et al. [1991]. *The Value of Pharmaceuticals: An Assessment of Future Costs for Selected Conditions*. Washington, D.C.: Battelle.

Brown, Ruth E., and Bryan R. Luce [1990]. *The Value of Pharmaceuticals: A Study of Selected Conditions to Measure the Contribution of Pharmaceuticals to Health Status*. Washington, D.C.: Battelle.

Buchan, James [1989]. "In the grip of takeover fever." *Financial Times* (London), 4 August, p. 8.

Burstall, M. L., and B. G. Reuben [1988]. *The "Costs of Non-Europe" in the Pharmaceutical Industry*. Research on the

"Costs of non-Europe," Basic Findings 15. Luxembourg: Commission of the European Communities.

Cady, J. F. [1975]. *Drugs on the Market. The Impact of Public Policy on the Retail Market for Prescription Drugs*. Lexington, Mass.: D. C. Heath.

_____ [1976]. *Restricted Advertising and Competition: The Case of Retail Drugs*. Washington, D.C.: American Enterprise Institute for Public Policy Research.

Callahan, Daniel [1987]. *Setting Limits, Medical Goals in an Aging Society*. New York: Simon and Schuster.

Canada. Department of Health and Welfare [1964]. *Provision, Distribution, and Cost of Drugs in Canada*. A study prepared for the Royal Commission on Health Services by the Research and Statistics Division. Ottawa: Queen's Printer.

_____ [1977]. *Annual Report, 1976-77*. Ottawa: Supply and Services Canada.

_____ [1984]. *National Health Expenditures in Canada 1970-1982*. Ottawa: the Department.

_____ [1989*a*]. *Charting Canada's Future*. A report of the Demographic Review. Ottawa: Supply and Services Canada.

_____ [1989*b*]. "Terms of reference, Advisory Panel on Biopharmaceutics and Pharmacokinetics." Bureau of Drug Surveillance, Ottawa.

_____ [1990]. *National Health Expenditures in Canada 1975-1987*. Ottawa: Supply and Services Canada.

Canada. Royal Commission on Health Services [1964]. *Report 1*. Ottawa: Queen's Printer.

_____ [1965]. *Report 2*. Ottawa: Queen's Printer.

Canada. Special Committee of the House of Commons on Drug Costs and Prices (Harley Committee) [1967]. *Second (Final) Report*. Ottawa: Queen's Printer.

Canadian Drug Manufacturers Association [1988]. "Submission to the Pharmaceutical Inquiry of Ontario." Toronto.

_____ [1989]. "Supplementary submission to the Pharmaceutical Inquiry of Ontario." Toronto.

_____ [1991*a*]. "When competition increases, drug prices drop." *The Straight Facts on Pharmaceutical Prices, Manufacturing and Research*, no. 2 (1 May).

_____ [1991*b*]. "Pseudo-generics." *The Straight Facts on Pharmaceutical Prices, Manufacturing and Research*, no. 3 (June 1).

Canadian Medical Association [1990]. *Guide to Prescription and Over-the-Counter Drugs*. Montreal: Reader's Digest Books.

Canadian Pharmaceutical Association [1989]. *Provincial Drug Benefit Programs*. Ottawa: The Association.

Canadian Press [1986]. "B.C. to investigate reports of inducements to druggists." *The Globe and Mail* (Toronto), 19 March, p. A8.

Carruthers, S. G. [1986]. "Summary of the composition and activities of the Drug Quality and Therapeutics Committee." Toronto.

_____ [1988]. Letter of resignation to the Minister of Health, 18 January.

Carruthers, S. G., et al. [1987]. *Drug Utilization. A Comprehensive Literature Review*. Toronto: Ministry of Health.

Chiles, Vernon K. [1988]. "Brief to the Pharmaceutical Inquiry of Ontario." Sarnia, Ontario.

Coburn, David, et al., eds. [1987]. *Health and Canadian Society, Sociological Perspectives*. 2nd edition. Markham, Ont.: Fitzhenry and Whiteside.

Cockerill, Rhonda, and Paul Williams [1989]. *Report on the 1989 Survey of the Dispensing Practices and Attitudes toward Prescription Drugs of Ontario Pharmacists*. In *Appendixes*, Pharmaceutical Inquiry of Ontario. Toronto: Ministry of Health.

Commission of Inquiry on the Pharmaceutical Industry [1985]. *Report*. Ottawa: Supply and Services Canada.

Commission on Pharmaceutical Services [1971]. *Pharmacy in a New Age*. Toronto: Canadian Pharmaceutical Association.

Commissioner, Combines Investigation Act [1950]. *Matches*. Ottawa: King's Printer.

Consumer Reports [1987]. "The big lie about generic drugs." (August):480-85.

Corvari, Ronald J. [1991]. "Strategic advertising behaviour and public policy in the Canadian pharmaceutical industry." Ph.D. thesis, Carleton University, Ottawa.

Crosthwait Consulting Services Ltd. [1986]. "A review of pharmaceutical pricing and data sources for the Ontario Drug Benefit program." Toronto.

Cureton, Glen L., and E. Deborah Jay [1990]. *An Assessment of Future Educational Needs for Community Pharmacists*. Prepared for National Association of Chain Drug Stores, Inc. Menlo Park, Calif.: SRI International.

Danforth, Douglas H., et al. [1982]. "Drug usage review. Part three: implementing the long-term care program." *Canadian Pharmaceutical Journal* 115, no. 1 (January):9.

Dao, Thi D. [1985]. "Cost-benefit and cost-effectiveness analysis of drug therapy." *American Journal of Hospital Pharmacy* 42 (April):791-802.

Di Masi, Joseph A., et al. [1991]. "The cost of innovation in the pharmaceutical industry." *Journal of Health Economics* 10 (June):107-42.

Director of Investigation and Research, Combines Investigation Act [1985]. *Annual Report for the Year Ended March 31, 1985*. Ottawa: Supply and Services Canada.

_____ [1989]. *Annual Report for the Year Ended March 31, 1989*. Ottawa: Supply and Services Canada.

Doubilet, Peter, et al. [1986]. "Use and misuse of the term 'cost effective' in medicine." *New England Journal of Medicine* 314, no. 4 (23 January):253-57.

Drummond, Michael, et al. [1988]. *Economic Evaluation in the Development of Medicines*. London: Office of Health Economics.

Dyer, Allan E. [1974]. "Ontario experience in selecting quality drugs." Paper presented to the American Association for the Advancement of Science, San Francisco, 27 February.

Economic Council of Canada [1979]. *Responsible Regulation*. Ottawa: Supply and Services Canada.

_____ [1989]. *Legacies*. Twenty-Sixth Annual Review. Ottawa: Supply and Services Canada.

Elston, Murray [1985]. "Statement by the Honourable Murray Elston, Minister of Health, to legislature re: legislation on drug pricing and consumer protection." Queen's Park, Toronto, 7 November.

Evans, Robert G. [1983*a*]. "We have seen the future, and they is us: health care and the greying of Canada." Discussion Paper, Department of Economics, University of British Columbia, Vancouver.

_____ [1983*b*]. "Health care in Canada: patterns of funding and regulation." *Journal of Health Politics, Policy and Law* 8, no. 1 (Spring):1-43.

_____ [1985*a*]. "The political economy of health care." Discussion Paper no. 85-24. Department of Economics, University of British Columbia, Vancouver.

_____ [1985*b*]. "Illusions of necessity: evading responsibility for choice in health care." *Journal of Health Politics, Policy and Law* 10, no. 3 (Fall):439-67.

_____ [1988]. "Squaring the circle: reconciling fee-for-service with global expenditure control." Discussion Paper 88:8D, Health Policy Research Unit, University of British Columbia, Vancouver.

_____ [1990]. "Accessible, acceptable and affordable: financing health care in Canada." Discussion Paper 90:19D, Health Policy Research Unit, University of British Columbia, Vancouver.

Evans, Robert G., and M. F. Williamson [1978]. *Extending Canadian Health Insurance: Options for Pharmacare and Denticare*. Ontario Economic Council Research Series, no. 13. Toronto: University of Toronto Press.

Evans, Roger W. [1983*a*]. "Health care technology and the inevitability of resource allocation and rationing decisions, Part I." *Journal of the American Medical Association* 249, no. 15 (April 15):2047-53.

_____ [1983*b*]. "Health care technology and the inevitability of resource allocation and rationing decisions, Part II." *Journal of the American Medical Association* 249, no. 16 (April 22/29):2208-19.

Expert Advisory Committee on Bioavailability [1990*a*]. *Bioavailability of Oral Dosage Formulations of Drugs Used for Systematic Effects. Report A: Drugs with Uncomplicated Characteristics*. Drugs Directorate. Ottawa: Health and Welfare Canada.

_____ [1990*b*]. *Bioavailability of Oral Dosage Formulations of Drugs Used for Systematic Effects. Report B: Modified Release Dosage Formulations*. Drugs Directorate. Ottawa: Health and Welfare Canada.

Fellegi, Ivan P. [1988]. "Can we afford an aging society?" *Canadian Economic Observer* 1, no. 10 (October):4.1-4.34.

Ferguson, James K. W., et al. [1973]. *Review of the Ontario Parcost Program*. Toronto: Ontario Council of Health.

Forbes, J. D., et al. [1982]. *Economic Intervention and Regulation in Canadian Agriculture*. Ottawa: Supply and Services Canada.

Giovinazzo, Nancy [1988]. "Letter to Pharmaceutical Inquiry of Ontario." Markham, Ontario.

Glaxo Canada Inc. [1988]. "Growing with Ontario, a submission to the Pharmaceutical Inquiry of Ontario." Toronto.

Goddard, Hans [1989]. "No frills." *Canadian Pharmaceutical Journal* 122, no. 6 (June): 306-8.

Gordon, John R. M. [1984]. *Report of the Commission on the Pricing of Multiple-Source Drug Products in Ontario*. Toronto: Ministry of Health.

_____ [1987]. "Chairman's recommendation to the Fee Negotiating Committee under Section 7 (9) of the Ontario Drug Benefit Act." Ministry of Health, Toronto, May.

_____ [1988]. "Chairman's recommendation to the Fee Negotiating Committee under Section 7 (9) of the Ontario Drug Benefit Act." Ministry of Health, Toronto, July.

Gordon, John R. M., and Christopher Maule [1989]. "What's at stake." *Canadian Pharmaceutical Journal* 122, no. 2 (February):74-78.

Gorecki, P. K. [1981]. "Regulating the price of prescription drugs in Canada: compulsory licensing, product selection, and government reimbursement programmes." Technical Report no. 8., Economic Council of Canada, Ottawa.

_____ [1982]. "The impact of the Parcost program on prescription drug prices in Ontario: some queries." *Canadian Public Policy* 8, no. 3, pp. 358-61.

_____ [1986a]. "The importance of being first: the case of prescription drugs in Canada." *International Journal of Industrial Organization* 4:371-95.

_____ [1986b]. "Monopoly, entry and predatory pricing: the Hoffman-LaRoche case." In *Firms and Markets: Essays in Honour of Basil Yamey*, eds. K. Tucker and C. Baden Fuller. London: Croom Helm, pp. 159-77.

_____ [1986c]. *Compulsory Patent Licensing of Drugs in Canada: Have the Full Price Benefits Been Realized?* Background study, Commission of Inquiry on the Pharmaceutical Industry. Ottawa: Supply and Services Canada.

_____ [1987a]. "Barriers to entry in the Canadian pharmaceutical industry: comments, clarifications and extensions." *Journal of Health Economics* 6:59-72.

_____ [1987b]. "Brief to the House of Commons Legislative Committee on Bill C-22, an Act to Amend the Patent Act and to Provide for Certain Matters in Relation Thereto." Ottawa.

_____ [1990a]. *Getting It Right: An Evaluation of Alternative Systems of the Organization on the Ontario Prescription Drugs Distribution System.* In *Appendixes*, Pharmaceutical Inquiry of Ontario. Toronto: Ministry of Health.

_____ [1990b]. "Protecting market share: oligopolists' strategies when faced with credible entrants. The case of the retail prescription drug market in Canada." Paper presented at the Canadian Economics Association Annual Meetings, Victoria, B.C., 1-3 June.

Gorecki, P. K., and Andrew B. Klymchuk [1980]. "Government intervention, regulation and competition in the prescription drug market in Canada: 1969-79." Paper presented at the Canadian Economics Association Annual Meetings, Montreal, 1-3 June.

Grabowski, Henry G. [1988]. "Medicaid patients' access to new drugs." *Health Affairs* 7 (Winter):102-14.

Green, Christopher [1985]. *Canadian Industrial Organization and Policy*. 2nd edition. Toronto: McGraw-Hill Ryerson.

Green Shield Prepaid Services Inc. [1988]. "A submission to the Pharmaceutical Inquiry of Ontario." Willowdale, Ontario.

Grenier, Gilles [1985]. "Health care costs in Canada: past and future trends." In *Income Distribution and Economic Security in Canada*, ed. François Vaillancourt. Vol. 1 of the studies commissioned as part of the research program of the Royal Commission on the Economic Union and Development Prospects for Canada. Toronto: University of Toronto Press, pp. 251-82.

Hall, Emmett M. [1980]. *Canada's National-Provincial Health Program for the 1980's: A Commitment for Renewal.* Ottawa: Supply and Services Canada.

Hepler, Charles D., and Linda M. Strand [1990]. "Opportunities and responsibilities in pharmaceutical care." *American Journal of Hospital Pharmacy* 47 (March):533-43.

Hirschman, Albert O. [1970]. *Exit, Voice and Loyalty*. Cambridge, Mass.: Harvard University Press.

Hlynka, John N., et al. [1981]. "Drug usage review. Part two: implementing the ambulatory program." *Canadian Pharmaceutical Journal* 114, no. 12 (December):467-70.

Hlynka, John N., and Douglas H. Danforth [1981]. "Drug usage review. Part one: designing the B.C. Pharmacare program." *Canadian Pharmaceutical Journal* 114, no. 11 (November): 421-23.

Hoffman-LaRoche Ltd. [1984]. "Brief to the Commission of Inquiry on the Pharmaceutical Industry (Eastman Commission)." Etobicoke, Ontario.

Hurley, Jeremiah [1989]. *An Examination of Access to Prescription Drugs in Ontario and an Evaluation of Selected Cost-Sharing Policies.* In *Appendixes*, Pharmaceutical Inquiry of Ontario. Toronto: Ministry of Health.

Johnston, Laurie [1987]. "'Boutique' pharmacies: next trendsetter." *Drug Merchandising* 68, no. 8 (June):35-40.

Lalonde, Marc [1974]. *A New Perspective on the Health of Canadians. A Working Document.* Ottawa: Department of Health and Welfare.

Leal, H. Allan, et al. [1980]. *Report of the Professional Organizations Committee.* Toronto: Ministry of the Attorney General.

Liang, J. Nellie, and Jonathan D. Ogur [1987]. *Restrictions on Dental Auxiliaries: An Economic Policy Analysis.* Bureau of Economics Staff Report. Washington, D.C.: Federal Trade Commission.

Lloyd, Alistair, and Beresford Stock [1990]. "The professional component index: a model for professional remuneration of pharmacists." *Australian Clinical Review* 10:157-59.

Macaulay, Robert W. [1989]. *Directions: Review of Ontario's Regulatory Agencies Report.* Prepared for the Management Board of Cabinet. Toronto: Queen's Printer.

Manga, Pran [1987]. "Equality of access and inequalities in health status: policy implications of a paradox." In *Health and Canadian Society, Sociological Perspectives*, eds. D. Coburn et al., pp. 637-48.

Marcantonio, Loree [1989]. "Impact on prescription volumes and quantities by the seniors copayment." B.C. Pharmacare, Vancouver, 5 May.

Maremont, Mark, and William C. Symonds [1991]. "A bitter pill for Glaxo?" *Business Week*, 29 April, p. 50.

Maritime Medical Care Incorporated [1991]. "The effects of copayment on utilization of the MSI seniors Pharmacare plan." Halifax.

Market Facts of Canada Ltd. [1988]. *Research Report: Ontario Pharmacist Study.* Toronto: Market Facts. (Reproduced in Upjohn Company of Canada [1988]).

Maule, Christopher [1989]. "Can retail pharmacists expect payment for counselling?" *Canadian Pharmaceutical Journal* 122, no. 11 (November):598-600.

_____ [1990]. "The review: a critic comments." *Canadian Pharmaceutical Journal* 123, no. 6 (June):268-70.

McAuley, Ronald G., et al. [1990]. "Five year results of the peer assessment program of the College of Physicians and Surgeons of Ontario." *Canadian Medical Association Journal* 143, no. 11, pp. 1194-99.

McCormack, James P., et al. [1990]. "Bioequivalence: just the facts please." *Canadian Pharmaceutical Journal* (September): 404-7.

McFetridge, Donald G., and Stanley Wong [1985]. "Predatory pricing in Canada: the law and the economics." *Canadian Bar Review* 63, no. 4 (December):685-733.

McKenna, Barrie [1990]. "Regulator defends Quebec drug stores." *The Globe and Mail* (Toronto), 21 April, p. B5.

McLaren, Christie [1988]. "Ontarians are overdrugged, underregulated, doctor says." *The Globe and Mail* (Toronto), 11 February.

McQuaig, Linda [1989]. "Generic drug group sues OMA, pharmaceutical film over video." *The Globe and Mail* (Toronto), 26 January, p. A3.

Medical Reform Group of Ontario [1988]. "Prescribing in Canada: a review of the literature." Brief to the Pharmaceutical Inquiry of Ontario, September.

Merck Frosst Canada Inc. [1988]. "A brief to the Pharmaceutical Inquiry of Ontario." Kirkland Lake, Ontario.

Mickleburgh, Rod [1991]. "Doctors' regulators turn ear to patients." *The Globe and Mail* (Toronto), 2 April, p. A1.

Muzondo, T. R., and B. Pazderka [1980]. *Professional Licensing and Competition Policy: Effects of Licensing on Earnings and Rates-of-Return Differentials*. Research Monograph no. 5, Bureau of Competition Policy. Ottawa: Supply and Services Canada.

Napke, E., and D.G.H. Stevens [1984]. "Excipients and additives: hidden hazards in drug products and in product substitution." *Canadian Medical Association Journal* 131 (December): 1449-52.

Nelson, Arthur A., et al. [1984]. "The effect of a Medicaid drug copayment program on the utilization and cost of prescription services." *Medical Care* 22, no. 8 (August):724-36.

New Brunswick. Commission on Selected Health Care Programs [1989]. *Report*. Fredericton: the Commission.

New Brunswick. Department of Health and Community Services [1991]. *Study of the Application of a Drug Utilization Review Model to Benzodiazepine Use in the Senior Citizen and Income Assistance Populations in New Brunswick*. Fredericton: the Department.

Nixon, Robert F. [1990]. *1990 Ontario Budget*. Toronto: Queen's Printer.

Nova Scotia. Department of Health [1990]. *Health Strategies for the Nineties: Managing Better Health*. Halifax: The Department.

Nova Scotia. Royal Commission on Health Care [1989]. *Towards a New Strategy*. Halifax: the Commission.

Novopharm Ltd. [1988]. "Submission to the Pharmaceutical Inquiry of Ontario." Scarborough, Ontario.

Ontario. Committee on the Healing Arts [1970]. *Report*. Toronto: Queen's Printer.

Ontario. Ministry of Community and Social Services [1989]. "Sweeney unveils $415 million in sweeping reforms to Ontario's social assistance system." News Release 89-336, Toronto, 18 May.

Ontario. Ministry of Health [1974]. *Drug Benefit Formulary*. No. 1. Toronto: Queen's Printer.

_____ [1975]. *Drug Benefit Formulary and Parcost Comparative Drug Index*. Toronto: Queen's Printer.

_____ [1976]. *Annual Report 1975/76*. Toronto: the Ministry.

_____ [1978]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 9. Toronto: Queen's Printer.

_____ [1979*a*]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 10, January. Toronto: Queen's Printer.

_____ [1979*b*]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 11, July. Toronto: Queen's Printer.

_____ [1980]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 12, January. Toronto: Queen's Printer.

_____ [1983]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 19, July. Toronto: Queen's Printer.

_____ [1984]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. No. 20, February. Toronto: Queen's Printer.

_____ [1985*a*]. *Drug Benefit Formulary/Parcost Comparative Drug Index*. Revised Addendum no. 20, January. Toronto: Queen's Printer.

_____ [1985*b*]. "Legislation promises to curb prescription drug prices." News Release 85/nr-238, Toronto, 7 November.

_____ [1987*a*]. "Government submission to the Chairman Dean John Gordon, the Fee Negotiating Committee, the Ontario Drug Benefit Act." Toronto.

_____ [1987*b*]. *Annual Report 1986/87*. Toronto: the Ministry.

_____ [1988*a*]. "Ministry establishes drug inquiry." News Release 88/nr-058, Toronto, 2 March.

_____ [1988*b*]. "Government submission to the Fee Negotiating Committee under the Ontario Drug Benefit Act." Unpublished paper, Toronto, June.

_____ [1988*c*]. "Presentation to the Pharmaceutical Inquiry of Ontario." Toronto, 17 October.

_____ [1988*d*]. "Minister takes action on Lowy recommendations." News Release 88/nr-323, Toronto, 15 December.

_____ [1988*e*]. "Managing by results: results abstract, 1987-88." Drug Programs Branch, Toronto.

_____ [1989*a*]. *Drug Benefit Formulary/Comparative Drug Index*. No. 26, January. Toronto: Queen's Printer.

_____ [1989*b*]. *Deciding the Future of Our Health Care: An Overview of Areas for Public Discussion*. Toronto: Queen's Printer.

_____ [1989*c*]. *Drug Benefit Formulary/Comparative Drug Index*. No. 27, July. Toronto: Queen's Printer.

_____ [1989*d*]. "Non-formulary benefits under Ontario Drug Benefit program (ODB)." Drug Programs Branch. Kingston, Ontario, March.

_____ [1990*a*]. "Non-formulary benefits under Ontario Drug Benefit program (ODB)." Drug Programs Branch. Kingston, Ontario, June.

_____ [1990*b*]. *Drug Benefit Formulary/Comparative Drug Index*. No. 29, July. Toronto: Queen's Printer.

_____ [1990*c*]. "Drug quality and therapeutics committee, administrative guidelines." Toronto, April.

_____ [1990*d*]. *Report of the International Conference on Quality Assurance and Effectiveness in Health Care*. Toronto: Queen's Printer.

_____ [1991]. *Drug Benefit Formulary/Comparative Drug Index*. No. 30, February. Toronto: Queen's Printer.

Ontario. Ministry of Industry, Trade and Technology [1991]. "Strategic analysis of the pharmaceutical industry in Ontario." Unpublished draft.

Ontario. Ministry of Treasury and Economics [1991]. *Managing Health Care Funding*. Supplementary paper, Ontario budget. Toronto: Queen's Printer.

Ontario. Premier's Council on Health Strategy [1989]. *From Vision to Action*. Report of the Health Care System Committee. Toronto: the Premier's Council.

Ontario. Standing Committee on Public Accounts [1980]. *First Report*. Legislative Assembly of Ontario, 4th session, 31st Parliament, Toronto, December.

Ontario. Standing Committee on Social Development [1986]. *Ontario Drug Benefit Act, Prescription Drug Cost Regulation Act*. Minutes of proceedings. Toronto: Legislative Assembly of Ontario.

Ontario Advisory Council on Senior Citizens [1985]. *Annual Report 1984/85*. Toronto: the Council.

Ontario College of Pharmacists [1988]. "Submission to the Pharmaceutical Inquiry of Ontario." Toronto.

Ontario Economic Council [1978]. *Government Regulation*. Toronto: OEC.

Ontario Medical Association [1988]. "Submission to the Pharmaceutical Inquiry of Ontario." Toronto.

Ontario Pharmacists' Association [1986]. "Presentation of the Council of the Ontario Pharmacists' Association to the Standing Committee of the Legislature on Social Development concerning Bill 54 – Ontario Drug Benefit Act, 1986 and Bill 55 – Prescription Drug Cost Regulation Act 1986." Toronto, 29 January.

_____ [1988*a*]. "Brief of the Ontario Pharmacists' Association for 1987-1988 fee negotiations with the Ontario Ministry of Health under the assistance of Dr. John Gordon." Toronto, 8 June.

_____ [1988*b*]. "Submission to the Pharmaceutical Inquiry of Ontario." Toronto.

Organisation for Economic Co-Operation and Development [1989]. *Predatory Pricing*. Paris: OECD.

Owen, Bruce M., and Ronald Braeutigam [1978]. *The Regulation Game: Strategic Use of the Administrative Process*. Cambridge, Mass.: Ballinger.

Patented Medicine Prices Review Board [1989]. *First Annual Report 1989*. Ottawa: the Board.

_____ [1991]. *Third Annual Report 1990*. Ottawa: The Board.

Pharmaceutical Advertising Advisory Board [1988]. "Brief outline of the PAAB." Pickering, Ontario.

Pharmaceutical Inquiry of Ontario [1988*a*]. "Quarterly report." Ministry of Health, Toronto, August.

_____ [1988*b*]. "Second quarterly report." Ministry of Health, Toronto, December.

_____ [1989 *a*]. "Third quarterly report." Ministry of Health, Toronto, April.

_____ [1989*b*]. "The role of the pharmacist." Discussion Paper, Toronto, August.

_____ [1989*c*]. "Fourth interim report." Ministry of Health, Toronto, December.

_____ [1990*a*]. *Prescriptions for Health*. Toronto: Ministry of Health.

_____ [1990*b*]. *Appendixes*. Toronto: Ministry of Health.

Pharmaceutical Manufacturers Association of Canada [1984*a*]. "Submission to the Gordon commission reviewing the PARCOST Comparative Drug Index/Ontario Drug Benefit Formulary." Ottawa, May.

_____ [1984*b*]. "Supplementary submission to the Commission of Inquiry on the Pharmaceutical Industry." Ottawa, September.

_____ [1988*a*]. "Submission to the Nova Scotia Royal Commission on Health Care." Ottawa.

_____ [1988*b*]. "Presentation to the Pharmaceutical Inquiry of Ontario." Ottawa.

Porter, Julian, et al. [1971]. *The Report of the Review Committee on Prescription Product Substitution*. Toronto.

Professional Management Associates Inc. [1987]. *Evaluation of Options to Reform the MAC/EAC Drug Reimbursement System Final Report*. Rockville, Maryland: PMA.

Quebec. Commission d'enquête sur les services de santé et les services sociaux [1988]. *Rapport*. Québec: Les Publications du Québec.

Quebec. Conseil Consultatif de Pharmacologie [1989]. "Famotidine co. 20 mg, 40 mg (Pepcid M.S.D.)." *Information Médicament*, July.

Quebec. Office des Professions du Québec [1977]. *Professional Fees in Private Practice: The Question of Regulation*. Québec: Bureau de l'Éditeur officiel.

Quebec. Régie de l'Assurance-maladie du Québec [1984]. *Statistiques annuelles, 1983*. Québec: Régie de l'Assurance-maladie du Québec.

_____ [1990]. *Statistiques annuelles, 1989*. Québec: Régie de l'Assurance-maladie du Québec.

Raison, Arnold V. [1989]. *The Evolution of Standards for Pharmaceutical Advertising in Canada*. Pickering, Ont.: Pharmaceutical Advertising Advisory Board.

Reeder, C. E., and Arthur A. Nelson [1985]. "The differential impact of copayment on drug use in a Medicaid population." *Inquiry* 22 (Winter):396-403.

Rosenthal, Elizabeth [1991]. "As costs of new drugs rise, hospitals stick by old ones." *New York Times*, 18 December, pp. A1.

Ross, Thomas M. [1966]. *Pharmacist Manpower in Canada*. A study prepared for the Royal Commission on Health Services. Ottawa: Queen's Printer.

Rucker, T. Donald [1983]. "Drug-utilization review: moving toward an effective and safe model." In *Society and Medication: Conflicting Signals for Prescribers and Patients*, ed. John P. Morgan and Doreen N. Kagan. Lexington, Mass.: D. C. Heath, pp. 25-51.

Saskatchewan. Commission on Directions in Health Care [1990]. *Future Directions for Health Care in Saskatchewan*. Regina: Government of Saskatchewan.

Saskatchewan. Department of Health [1986]. *Formulary*. 23rd edition, July. Regina: Minister of Health.

_____ [1989]. *Formulary*. 28th edition, January. Regina: Minister of Health.

_____ [1990]. *Formulary*. 31st edition, July. Regina: Minister of Health.

Saskatchewan. Health Prescription Drug Plan [1984]. *Annual Report 1983-84*. Regina: Government of Saskatchewan.

_____ [1987]. *Annual Report 1986-87*. Regina: Government of Saskatchewan.

_____ [1988]. *Annual Report 1987-88*. Regina: Government of Saskatchewan.

Saskatchewan. Review Committee to the Minister of Health [1989]. *Study into the Growth in Use of Health Services*. Regina: Ministry of Health.

Schieber, George J. [1987]. *Financing and Delivering Health Care: A Comparative Analysis of OECD Countries*. Paris: OECD.

Schnell, B. R. [1981]. "A review of the use of prescription drugs in Saskatchewan." *Canadian Pharmaceutical Journal* (July): 267-70.

Schwartz, Alan M. [1989]. *Striking a New Balance: A Blueprint for the Regulation of Ontario's Health Professions*. Toronto: Ministry of Health.

Segal, Harold J. [1973]. "Changes in pharmacy practice: Ontario's PARCOST program." *Canadian Pharmaceutical Journal* 107 (November):346-51.

Shulman, Shelia R., and Barbara W. Richard [1988]. "The 1987 Canadian patent law amendments: revised pharmaceutical compulsory licensing provisions." *Food Drug Cosmetic Law Journal* 43, no. 5 (September):745-57.

Silversides, Ann [1985*a*]. "Survey finds druggists routinely overcharge." *The Globe and Mail* (Toronto), 23 September, pp. 1-4.

_____ [1985*b*]. "Drug overcharging surprises watchdog." *The Globe and Mail* (Toronto), 26 September, pp. 1-2.

_____ [1986]. "Pharmacists' college ignores evidence that some of its own council overcharged." *The Globe and Mail* (Toronto), 18 August, p. A1.

Soumerai, Stephen B., et al. [1987]. "Payment restrictions for prescription drugs under Medicaid: effects on therapy, cost, and equity." *New England Journal of Medicine* (August 27): 550-60.

Soumerai, Stephen B., et al. [1989]. "Improving drug prescribing in primary care: a critical analysis of the experimental literature." *Milbank Quarterly* 67, no. 2, pp. 268-317.

Soumerai, Stephen B., et al. [1990]. "Withdrawing payment for non-scientific drug therapy: intended and unexpected effects of a large-scale natural experiment." *Journal of the American Medical Association* 263, no. 6 (February 9):831-39.

Soumerai, Stephen B., and Jerry Avorn [1986]. "Economic and policy analysis of university-based detailing." *Medical Care* 24, no. 4, pp. 313-31.

Spitzer, Walter O., et al. [1988]. "Benefits, risks and costs of prescription drugs in Ontario: a scientific basis to evaluate policy options." A submission of the Interuniversity Working Group to the Lowy Commission of Inquiry, Toronto, November.

Stevenson, H. Michael, et al. [1988]. "Medical politics and Canadian Medicare: professional response to the Canada Health Act." *Milbank Quarterly* 66, no. 1, pp. 65-104.

Stigler, George [1975]. "The theory of economic regulation." In *The Citizen and the State, Essays on Regulation*, ed. G. Stigler. Chicago: University of Chicago Press.

Strong, A. E., and J. Harvey [1989]. "The Ontario pharmaceutical market analysis." Montreal and Toronto.

Sutton, Frances [1988]. *Trends in Pharmaceutical Benefit Expenditure over the Last Decade*. Economics Unit and National Health Statistics Centre. Wellington, New Zealand: Department of Health.

Tarasofsky, Abraham [1984]. *The Subsidization of Innovation Projects by the Government of Canada*. Economic Council of Canada. Ottawa: Supply and Services Canada.

Task Force on the Cost-Effectiveness of Pharmaceutical Products and Pharmacy Services [1989]. *Final Report*. Washington, D.C.: American Pharmaceutical Association.

Taylor, J. Allyn, et al. [1977]. *Report of the Joint Advisory Committee of the Government of Ontario and the Ontario Medical Association on Methods to Control Health Care Costs*. Toronto.

Taylor, Malcolm G. [1987]. "The Canadian health-care system: after Medicare." In *Health and Canadian Society, Sociological Perspectives*, eds. D. Coburn et al., Markham, Ont.: Fitzhenry and Whiteside, pp. 73-101.

The Economist (London) [1989]. "Drug company mergers, love potion no. 9." 5 August, pp. 58-59.

_____ [1990]. "The doctors' dilemma." 27 January, pp. 69-70.

Trebilcock, Michael J., et al. [1979]. *Profession Regulation. A Staff Study of Accountancy, Architecture, Engineering and Law in Ontario*. Prepared for the Professional Organizations Committee. Toronto: Ministry of the Attorney General.

United States. Department of Health and Human Services, Office of Inspector General, Office of Evaluation and Inspections [1989]. *Medicare Drug Utilization Review*. Boston: Office of Inspector General.

_____ [1990*a*]. *The Clinical Role of the Community Pharmacist*. Boston: Office of Inspector General.

_____ [1990*b*]. *State Discipline of Pharmacists*. Boston: Office of Inspector General.

_____ [1990*c*]. *Symposium on Drug Utilization Review Issues: Proceedings*. Boston: Office of Inspector General.

_____ [1991]. *Strategies to Reduce Medicaid Drug Expenditures*. Boston: Office of Inspector General.

United States. Federal Register [1987]. "Medicare and Medicaid programs; limits on payments for drugs; final rule." Part III. Health Care Financing Administration, Department of Health and Human Services, 52, no. 147 (July 31):28, 648-58.

United States. General Accounting Office [1991]. *Canadian Health Insurance: Lessons for the United States*. Report no. GAO/HRD-91-90. Washington, D.C.: Government Accounting Office.

United States. Office of Technology Assessment [1980*a*]. *The Implications of Cost-Effectiveness Analysis of Medical Technology*. Washington, D.C.: U.S. Government Printing Office.

_____ [1980*b*]. *Methodological Issues and Literature Review*. Background Paper no. 1. Washington, D.C.: U.S. Government Printing Office.

United States. Senate, Special Committee on Aging [1991]. "The drug manufacturing industry: a prescription for profits." A staff report, Washington, D.C.

Upjohn Company of Canada [1984]. "Submission to the Commission of Inquiry into the Pharmaceutical Industry." Don Mills, Ontario.

_____ [1988]. "Submission to the Pharmaceutical Inquiry of Ontario, the Lowy Commission." Don Mills, Ontario.

Weinstein, Milton C., and William B. Stason [1977]. "Foundations of cost-effectiveness analysis for health and medical practices." *New England Journal of Medicine* 296, no. 13 (March 31):716-21.

Williams, A. Paul, and Rhonda Cockerill [1989]. *Report on the 1989 Survey of the Prescribing Experiences and Attitudes toward Prescription Drugs of Ontario Physicians*. In *Appendixes*, Pharmaceutical Inquiry of Ontario. Toronto: Ministry of Health.

Wolf, Charles [1988]. *Markets or Governments: Choosing between Imperfect Alternatives*. Cambridge, Mass.: MIT Press.

Woods Gordon [1981]. *Ontario Drug Benefit Plan Impact Study*. Two volumes. Toronto: Woods Gordon.

Yamey, Basil S. [1972]. "Predatory price cutting: notes and comments." *Journal of Law and Economics* 15, no. 1 (April): 129-42.

Economic Council
of Canada

Conseil économique
du Canada

Ontario

Ministry
of
Health

Ministère
de
la Santé